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UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re: PURDUE PHARMA L.P., *et al.*, Debtors.[1]	Chapter 11 Case No. 19-23649 (RDD) Jointly Administered

THE RAYMOND SACKLER FAMILY'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

[1] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. ("PPLP") (7484), Purdue Pharma Inc. ("PPI") (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717) and SVC Pharma Inc. (4014) (collectively, the "**Debtors**"). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

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TABLE OF DEFINED TERMS

Unless otherwise defined below, capitalized terms in these Proposed Findings of Fact and Conclusions of Law are as defined in the Debtors' Sixth Amended Joint Chapter 11 Plan of Reorganization (ECF No. 3185), as amended.

2005 Compliance Charter	Compliance Charter adopted by the Board in October 2005 (JX-2012)
2007 Civil Settlement Agreement	The May 2007 settlement agreement entered into between PPLP, The Purdue Frederick Company, DOJ, the OIG, the United States Office of Personnel Management, the United States Department of Defense TRICARE Management Activity, and the United States Department of Labor Office of Workers' Compensation Programs, embodied in the Settlement Agreement attached as Attachment D to the Criminal Information in *United States v. The Purdue Frederick Co.*, 1:07-cr-0029 (W.D. Va. May 10, 2007), ECF No. 5-4 (JX-1897)
2007 Compliance Charter	Compliance Charter adopted by the Board in May 2007 (JX-2013)
2007 Federal Settlement	The May 2007 civil settlement between Purdue Frederick and the DOJ, embodied in the 2007 Civil Settlement Agreement
2007 Guilty Plea	The May 2007 federal guilty plea entered by Purdue Frederick, embodied in the Plea Agreement entered in *United States v. The Purdue Frederick Co.*, 1:07-cr-0029 (W.D. Va. May 10, 2007), ECF No. 6, (JX-1899)
2007 State Consent Judgments	The State Consent Judgments that Purdue entered into with the 26 States and the District of Columbia comprising the Consent Judgment States in mid-2007
ADD	Abuse and Diversion Detection
ADD Covered Person	A person at Purdue who was in contact with HCPs or pharmacists
ADD Program	Purdue's Abuse and Diversion Detection Program

ADD Report	Report that had to be filed by any ADD Covered Person after learning about a circumstance or making an observation that could be indicative of potential abuse or diversion
ADF	Abuse-deterrent formulation
Adverse Event	Any unanticipated experience or side effect associated with the use of a drug, whether or not it is considered related to the product
Agreed Statement of Facts	The Agreed Statement of Facts Purdue entered into in 2007 in connection with its guilty plea; *see* Information and Attachment B thereto, *United States* v. *The Purdue Frederick Co.*, 1:07-cr-0029 (W.D. Va. May 10, 2007), ECF No. 5-2 (JX-1895)
AMA	American Medical Association
AOD	August 2015 Assurance of Discontinuance between New York State and Purdue (JX-1889)
Blouin Supplemental Declaration or Suppl. Decl.	The August 4, 2021 Supplemental Declartion of Jennifer Blouin
Blouin Report or Rept.	The June 15, 2021 Expert of Jennifer Blouin with Exhibits and Appenidices (corrected as of July 26, 2021) (JX-0425 – JX-0430)
Board	The board of directors of PPI
CA AG FAC	The First Amended Complaint filed in *People of the State of California v. Purdue Pharma L.P.*, Case No. 19STCV19045 (Cal. Super. Ct., L.A. Cnty. Oct. 2, 2019)
CBE	Changes-being-effected process to change an FDA approved label
CDC	Centers for Disease Control and Prevention

Chakreborty Report or Rept.	The June 15, 2021 Expert Report of Maureen M. Chakraborty, Ph.D. with exhibits and appendices (corrected as of July 26, 2021) (JX1937 – JX-1977)
CIA	Purdue's Corporate Integrity Agreement, *see* Information, Attachment E, *United States* v. *The Purdue Frederick Co.*, 1:07-cr-0029 (W.D. Va. May 10, 2007), ECF Nos. 5-5, 5-6 (JX-1891)
Claimants	The Estate and Non-Estate Claimants
Claims	The Estate Claims and the Non-Estate Claims
CO AG FAC	The First Amended Complaint filed in *State of Colorado v. Purdue Pharma*, *L.P.*, Case No. 18-CV-33300 (Colo. Dist. Ct., Denver Cnty. July 1, 2019) (JX-2212)
Consent Judgment States	The 26 states and the District of Columbia that entered into the 2007 State Consent Judgments with Purdue: Arizona, Arkansas, California, Connecticut, the District of Columbia, Idaho, Illinois, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Montana, Nebraska, Nevada, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington, and Wisconsin
CT AG SAC	Second Amended Complaint filed in *State of Connecticut v. Purdue Pharma L.P.*, No. X07 HHD-CV-19-6105325-S (Conn. Super. Ct., Hartford Cnty. July 1, 2019)
CSA	Controlled Substance Act(s)
DE AG Compl.	Complaint filed in *State of Delawre v. Sackler*, No. N19C-062 MMJ CCLD (Del. Super. Ct., New Castle Cnty. Sept. 9, 2019)
DDLA	Drug Dealer Liability Act(s)
Debtors	The debtors in the case *In re Purdue Pharma L.P.*, Case No. 19-23649-rdd (Bankr. S.D.N.Y.), including Purdue and Rhodes
DEA	U.S. Drug Enforcement Administration

Debtors' Informational Brief	Debtors' Informational Brief, *In re Purdue Pharma L.P.*, Case No. 19-23649-rdd (Bankr. S.D.N.Y. Sept. 9, 2019), ECF No. 17
Distributions	$10.4 billion which comprise the US Partner Distributions, Ex-US Distributions, and Tax Distributions
DOJ	The U.S. Department of Justice
DS or Disclosure Statement	The Disclosure Statement for Fifth Amended Plan of Reorganization at 138-39, *In re Purdue Pharma L.P.*, No. 19-23649-rdd (Bankr. S.D.N.Y. June 3, 2021) (ECF No. 2983)
E2E	The "Evolve to Excellence" program recommended to Purdue by McKinsey
ER	Extended-release
ERO	Extended-release opioid
Estate Claimants	Holders of Estate Claims, *i.e.*, the Debtors
Estate Claims	Claims against the Sackler Family Members and their trusts held by the Estate
Ex-US Distributions	$1,546.6 billion in distributions by PPLP to PRALP and invested in the IACs
FDA	U.S. Food and Drug Administration
Form of State Settlement and Release	Form of settlement agreement between Purdue and each of the 48 States and the District of Columbia comprising the Medicaid Settlement States, which was part of Purdue's 2007 Federal Settlement; *see* Information, Attachment M, *United States v. The Purdue Frederick Co.*, 1:07-cr-0029 (W.D. Va. May 10, 2007), ECF No. 5-14 (JX-1898)
Former Directors	Raymond Sackler Family Members who served on the Board: Beverly Sackler, David Sackler, Jonathan Sackler, and Richard Sackler

GAO	The U.S. Government Accountability Office
Hamermesh Report or Rept.	The June 15, 2021 Expert Report of Professor Lawrence A. Hamermesh with exhibits (Corrected July 12, 2021) (JX-0470 – JX-0474)
HCPs	Health care practitioners
HHS	U.S. Department of Health and Human Services
Huron	Huron Consulting Services LLC
IAC	Independent Associated Company (foreign affiliates of PPLP ultimately owned by the Sackler Families)
ID AG Compl.	The complaint filed in *State of Idaho v. Purdue Pharma L.P.*, Case No. CV01-19-10061 (Idaho Dist. Ct., Ada Cnty. June 3, 2019)
IR	Immediate release opioid
IRO	Independent Review Organization engaged by Purdue pursuant to the CIA (Huron).
Ives Declaration or Decl.	The August 2, 2021 Declaration of Stephen A. Ives
KOL	Key opinion leader
Ky. Consent Judgment	The Consent Judgment entered into in *In re Purdue Pharma L.P.*, No. 07-C-00740 (Ky. Cir. Ct., Franklin Cnty. May 8, 2007) (JX-1900)
Lynam Declaration or Decl.	The August 2, 2021 Declaration of Garrett Lynam
MA AG FAC	First Amended Complaint filed in *Commonwealth of Massachusetts v. Purdue Pharma L.P.*, C.A. No. 1884-cv-1808 (Mass. Super. Ct. Suffolk Cnty. Jan. 31, 2019) (JX-2503)

MA AG OC	Complaint filed in *Commonwealth of Massachusetts v. Purdue Pharma L.P.*, C.A. No. 1884-cv-1808 (Mass. Super. Ct., Suffolk Cnty. June 12, 2018) (JX-2209)
Martin Report or Rept.	The July 26, 2021 Amended Expert Report of Timothy J. Martin with Exhibits (JX-1914 – HX1923)
McKinsey	McKinsey & Company
MD AG SOC	The Amended Statement of Charges filed in *Consumer Prot. Div. v. Purdue Pharma, L.P.*, CPD Case No. 19-023-311366, OAH Case No. 1923474 (Md. Consumer Prot. Div. May 29, 2019)
ME AG FAC	The Complaint filed in *State of Maine v. Purdue Pharma L.P.*, Case No. CV-19-112 (Me. Super. Ct., Kennebec Cnty. June 3, 2019)
Medicaid Settlement States	The 48 States and the District of Columbia who settled Medicaid Claims with Purdue in 2007, which included all States except Kentucky (which settled later) and West Virginia (which settled earlier)
MMEs	Morphine milligram equivalents
MN AG FAC	The First Amended Complaint filed in *State of Minnesota v. Purdue Pharma L.P.*, Case No. 27-CV-18-10788 (Minn. Dist. Ct., Hennepin Cnty. July 8, 2019) (JX-2213)
MNP	MNP Consulting Limited
Mortimer Sackler Family	All Persons who are descendants of Mortimer D. Sackler, all current and former spouses of such descendants, and all current and former spouses of Mortimer D. Sackler or any of their respective descendants
NAAG	The National Association of Attorneys General
NAVIPPRO ASI-MV	National Addictions Vigilance Intervention and Prevention Program, Addiction Severity Index-Multimedia Version
NDA	New drug application filed with the FDA proposing that it approve a new pharmaceutical for sale and marketing in the U.S.

NDCP	Office of National Drug Control Policy of the White House
NIDA	National Institute of Drug Abuse, part of NIH
NIH	National Institutes of Health
Non-Estate Claimants	Holders of Non-Estate Claims
Non-Estate Claims	Claims asserted against the Sackler Family Members and their trusts by claimants other than the Estate, including the States, Tribes, municipalities and private plaintiffs
NYAG	New York Attorney General
NYAG FAC	First Amended Complaint filed in *People of the State of New York v. Purdue Pharma L.P.*, No. 400016/2018 (N.Y. Sup. Ct., Suffolk Cnty. Mar. 28, 2019) (JX-2211)
OIG	Office of Inspector General of HHS
OIG Standards and the Sentencing Guidelines	OIG HEALTH CARE COMPLIANCE PROGRAM TIPS, U.S. DEP'T OF HEALTH AND HUMAN SERVS., *available at* https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf (last visited Aug. 1, 2021) (JX-2201)
OMS or OMS Program	Purdue's Order Monitoring System
Plan	The Debtors' Sixth Amended Joint Chapter 11 Plan of Reorganization (ECF No. 3185), as amended
PMP	Purdue's Promotion Monitoring Program
POC	Proof of Claim Number 150563 filed by the States and Territories and other governmental entities listed at Schedule 1 to the POC
PPI	Purdue Pharma Inc.

PPLP	Purdue Pharma L.P.
PRALP	Pharmaceutical Research Associates L.P. f/k/a/ Purdue Holdings L.P.
PROP	Physicians for Responsible Opioid Prescribing
Purdue	PPLP and PPI
Purdue 2020 Civil Settlement	The October 2020 settlement of civil claims between Purdue and DOJ, OIG, the Defense Health Agency, the Tricare Program, the Office of Personnel Management, the Federal Employees Health Benefits Program, and the Indian Health Service, with addenda, *available at* https://www.justice.gov/opa/press-release/file/1329571/download (JX-2095)
Purdue 2020 Plea Agreement	The October 2020 plea agreement between Purdue and DOJ, with exhibits, addenda and schedules, *available at* https://www.justice.gov/opa/press-release/file/1329571/download (JX-2094)
Purdue 2020 Settlement	The Settlement embodied in the Purdue 2020 Civil Settlement and the Purdue 2020 Plea Agreement
Purdue Addendum A	Addendum A to the Purdue 2020 Civil Settlement, containing allegation by DOJ that were all denied by Purdue
Purdue Frederick	The Purdue Frederick Company, Inc.
Raymond Sackler Family	All persons who are descendants of Raymond R. Sackler, all current and former spouses of such descendants, and all current and former spouses of Raymond R. Sackler or any of their respective descendants
Region Zero or Region 0	Purdue's Do Not Call list for HCPs and pharmarcists
Relevant Period	From June 1, 2007 through December 2018
Rhodes	Collectively Rhodes Pharmaceuticals Inc., Rhodes Technologies Inc. and

	Rhodes Pharmaceuticals L.P.
RI AG SAC	The Second Amended Complaint filed in *State of Rhode Island v. Purdue Pharma L.P.*, C.A. No. PC-2018-4555 (R.I. Super. Ct., Providence Cnty. Dec. 20, 2019)
RI v. Sackler OC	The Complaint filed in *State of Rhode Island v. Sackler.*, C.A. No. PC-2019-9399 (R.I. Super. Ct., Providence Cnty. Sept. 11, 2019) (JX-2214)
ROC	Report of Concern—report of an alleged occurrence of misuse, abuse or diversion of a Purdue opioid medication, other than an Adverse Event
Sackler 2020 Settlement	The October 2020 settlement of civil claims between certain members of the Sackler Families and DOJ, OIG, the Defense Health Agency, the Tricare Program, the Office of Personnel Management, the Federal Employees Health Benefits Program, and the Indian Health Service, with addenda, *available at* https://www.justice.gov/opa/press-release/file/1329736/download (JX-2096)
Sackler Addendum A	Addendum A to the Sackler 2020 Settlement, containing allegations against the settling Sackler Family Members, all of which are denied by the settling Sackler Family Members
Sackler Declaration or Decl.	The August 5, 2021 Declaration of David A. Sackler
Sackler Family, Sackler Families or Sacklers	Collectively, all Persons who are descendants of either Raymond R. Sackler or Mortimer D. Sackler, all current and former spouses of such descendants, and all current and former spouses of Raymond R. Sackler, Mortimer D. Sackler or any of their respective descendants
SAMHSA	The U.S. Substance Abuse and Mental Health Services Administration
Schedule A	Schedule A to the Purdue 2020 Plea Agreement, containing a narrow set of fact admitted by Purdue as part of the 2020 Purdue Settlement
Schedule II Drugs	Drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous. This scheduling scheme is described on the website of the DEA, *Drug*

	Scheduling, DEA, https://www.dea.gov/drug-information/drug-scheduling (JX-2197)
Schedule III Drugs	Drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Schedule III drugs abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV. This scheduling scheme is described on the website of the DEA, *Drug Scheduling*, DEA, https://www.dea.gov/drug-information/drug-scheduling (JX-2197)
Shareholder Settlement Amount	The $4.325 billion to be paid into the estate, for the benefit of its creditors, pursuant to the Shareholder Settlement
Shareholder Settlement or Shareholder Settlement Agreement	The settlement and release of the Sackler Family under the terms of the Plan and the Settlement Term Sheet in DS Appendix G
Side A	The Mortimer Sackler Family
Side B	The Raymond Sackler Family
SOM or SOM Program	Purdue's Suspicious Order Monitoring Program
SOP	Standard Operating Procedure
State and Territory Claimants	States and Territories listed on Schedule 1 to the POC
Tax Distributions	$4,680.2 billion in tax distributions made by Purdue to or for the ultimate benefit of members of the Sackler Families
Territories	Territories listed on Schedule 1 of the POC
Trompetta Declaration or Decl.	The July 26, 2021 Declaration of Carl Trompetta

US Partner Distributions	$4,119.8 billion in cash distributions by PPLP to its limited partners
Third Party Releases	Releases of the Non-Estate Claims under the Plan
UT AG Citation	The Administrative Citation filed in *In the Matter of Purdue Pharma L.P.*, DCP Legal File No. CP-2019-005, DCP Case No. 107102 (Utah Div. Consumer Prot. Mar. 8, 2019)
VT AG Compl.	Complaint filed in *State of Vermont v. Sackler*, No. 469-5-19 Cncv (Vt. Super. Ct., Chittenden Cnty. May 21, 2019)
Website	Side B's website, https://www.judgeforyourselves.info/
WHO	World Health Organization

PROPOSED FINDINGS OF FACT

I. PURDUE, OXYCONTIN, INADEQUATE PAIN TREATMENT AS A PUBLIC HEALTH ISSUE, AND THE FDA'S CONTINUING DETERMINATION THAT OXYCONTIN IS SAFE AND EFFECTIVE TO TREAT PAIN

1. PPLP is a Delaware limited partnership headquartered in Stamford, Connecticut that manufactures prescription opioid medications, as well as non-opioid products.[2]

2. PPLP's prescription opioid medications include OxyContin, a Schedule II extended release opioid ("**ERO**") approved by the Food and Drug Administration ("**FDA**") in 1995 whose active pharmaceutical ingredient is oxycodone.[3]

3. OxyContin is the main focus of virtually all of the Non-Estate Claims asserted by the States, Territories, Tribes, other Domestic Governmental Entities and private claimants ("**Non-Estate Claimants**" or "**Claimants**") against Purdue and the Sacklers.[4]

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[2] JX-2089 at ¶¶1, 5 (June 20, 2019 PPLP Fifth Amended and Restated Partnership Agreement) (PPLPUCC500143435); *see also* Debtors' Informational Brief at 8, *In re Purdue Pharma L.P.*, Case No. 19-23649-rdd (Bankr. S.D.N.Y. Sept. 9, 2019), ECF No. 17 ("**Debtors' Informational Brief**"). PPLP's general partner is Purdue Pharma Inc. ("**PPI**," together with PPLP, "**Purdue**")), a New York corporation, and its limited partner is Pharmaceutical Research Associates L.P. f/k/a/ Purdue Holdings L.P. ("**PRALP**"), a Delaware limited partnership. *See* JX-2089 (June 20, 2019 PPLP Fifth Amended and Restated Partnership Agreement) (PPLPUCC500143435); JX-2087 (PPI Certificate of Amendment of Certificate of Incorporation of PPI) (PPLP004415886) at -888. Certain members of the Sackler family— Beverly Sackler, David Sackler, Ilene Lefcourt Sackler, Jonathan Sackler, Mortimer D.S. Sackler, Richard Sackler, and Theresa Sackler—previously served on the PPI Board (the "**Former Directors**").

[3] *See* Purdue Products, https://www.purduepharma.com/healthcare-professionals/products/; Debtors' Informational Brief at 8, 11 n.12. Purdue's prescription opioid medications also include Butrans, a Schedule III seven-day, transdermal patch pain opioid approved by the FDA in 2010 whose API is buprenorphine, and Hysingla, a Schedule II extended release opioid approved by the FDA in 2014 whose API is hydrocodone. *Id*.

[44] *See, e.g.*, First Amended Complaint at ¶5, *New York v. Purdue Pharma L.P.*, No. 400016/2018 (N.Y. Sup. Ct., Suffolk Cnty. Mar. 28, 2019) ("**NYAG FAC**") ("The taproot of the opioid epidemic is easy to identify: OxyContin."); POC ¶9 ("Purdue not only continued its deceptive scheme to misrepresent OxyContin's addictive properties and dangers; it also worked shamelessly to increase the frequency, dosage, and time period for OxyContin prescriptions to achieve greater

4. Prescription opioid medications like OxyContin "are powerful pain-reducing medications" that "have both benefits as well as potentially serious risks."[5]

5. Since all opioids are controlled substances,[6] the prescription opioid industry is highly regulated.[7]

6. Most opioid pain medications approved by the FDA, including OxyContin, are Schedule II drugs.[8]

7. Unlike Schedule I drugs, which are illegal and deemed by the DEA to have "no currently accepted medical use and a high potential for abuse," Schedule II medications like OxyContin have a legitimate medical purpose, but also a "high potential for abuse" which may lead to "severe psychological or physical dependence."[9]

8. By contrast, Schedule III medications—like testosterone, codeine and Purdue's transdermal opioid patch, Butrans—are drugs with "a moderate to low potential for physical and

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profits from branded and unbranded product."); *id*. at 2 ("Purdue's Manufacturing and Aggressive Marketing of OxyContin").

[5] *See* FDA, OPIOID MEDICATIONS, https://www.fda.gov/drugs/information-drug-class/opioid-medications.

[6] *See* DEA, Drugs of Abuse, A DEA Resource Guide 49, (ed. 2020), https://www.dea.gov/sites/default/files/2020-04/Drugs%20of%20Abuse%202020-Web%20Version-508%20compliant-4-24-20_0.pdf.

[7] *See, e.g.*, DEA, What We Do, https://www.dea.gov/what-we-do ("DEA's mission also includes … [r]egulating the manufacture and distribution of controlled pharmaceuticals.").

[8] *See* DEA, Drugs of Abuse, A DEA Resource Guide 26–28 (ed. 2020 Ed.) https://www.dea.gov/sites/default/files/2020-04/Drugs%20of%20Abuse%202020-Web%20Version-508%20compliant-4-24-20_0.pdf (list of Schedule II substances).

[9] *See* DEA, *Drug Scheduling*, https://www.dea.gov/drug-scheduling (last visited on July 28, 2021).

psychological dependence."[10]

9. Chronic pain was a recognized public health crisis when OxyContin was developed and first approved by the FDA in 1995, and it remains one today.

10. In 1986, the World Health Organization ("**WHO**") declared that "inadequate treatment of cancer and noncancer pain is a serious public health concern."[11]

11. Many national health organizations, as well as the DEA, acknowledged this public health problem.[12]

12. In 2004, the WHO supported efforts to treat chronic pain as a "disease in its own right" and to recognize that "[c]hronic pain is one of the most underestimated health care problems in the world today."[13]

13. According to a 2018 CDC report, chronic pain remains "one of the most common reasons adults seek medical care."[14]

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[10] *Id.*

[11] JX-2181 (U.S. Gen. Accounting Office, GAO-04-110, Prescription Drugs: OxyContin Abuse And Diversion And Efforts to Address the Problem (2003)).

[12] *See* JX-2179 (10/23/01 Joint Statement from 21 Health Organizations and the DEA) ("Undertreatment of pain is a serious problem in the United States, including pain among patients with chronic conditions and those who are critically ill or near death."); JX-2178 (1998 NIH Report) at 2 ("Pain is a significant national health problem ... costing the American public more than $100 billion each year."); JX-2224 (May 2004 Model Policy Treatment of Pain) at 1 ("The undertreatment of pain is recognized as a serious public health problem that results in a decrease in patients' functional status and quality of life …").

[13] *See* WHO, WORLD HEALTH ORGANIZATION SUPPORTS GLOBAL EFFORT TO RELIEVE CHRONIC PAIN (Oct. 11, 2004), https://www.afro.who.int/news/world-health-organization-supports-global-effort-relieve-chronic-pain.

[14] *See* CDC, PREVALENCE OF CHRONIC PAIN AND HIGH-IMPACT CHRONIC PAIN AMONG ADULTS–UNITED STATES, 2016 at (2018), https://www.cdc.gov/mmwr/volumes/67/wr/mm6736a2.htm ("In 2016, approximately 20% of U.S. adults had chronic pain (approximately 50 million), and 8% of U.S. adults (approximately 20 million) had high-impact chronic pain. … Chronic pain contributes to an estimated $560 billion each year in direct medical costs, lost productivity, and disability

14. The FDA and the medical community recognize that, although opioid medications present risks of abuse, misuse, and addiction that can result in overdose, addiction and death,[15] they also are an important tool for the management of chronic pain caused by a host of conditions—including trauma, burns, sickle cell disease, cancer, and cancer therapies—and for palliative care.[16]

15. The FDA's website recognizes that: "According to the National Institutes of Health, studies have shown that properly managed medical use of opioid analgesic compounds (taken exactly as prescribed) is safe, can manage pain effectively, and rarely causes addiction."[17]

16. It is the FDA's job to strike the proper balance between the benefits of a

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programs."); *see also* JX-2326 (Mark Rosenberg, *Undertreated Pain Epidemic: Multi-Modality Approach to Pain Management*, 15 J. MANAGED CARE MED. 1 (2012)) at 30 ("Pain is … one of the most prevalent medical complaints in the U.S. … The total annual cost of poorly controlled persistent pain most likely exceeds $100 billion per year.").

[15] *See, e.g.*, JX-2120 (Sept. 26, 2018 FDA, OXYCONTIN FULL PRESCRIBING INFORMATION, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022272s039lbl.pdf ("**2018 Label**")) at 1.

[16] *See* U.S. DEP'T OF HEALTH & HUMAN SERVS. ("**HHS**"), PAIN MANAGEMENT BEST PRACTICES INTER-AGENCY TASK FORCE REPORT at 11 (May 9, 2019), https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf; NAT'L HEART, LUNG, AND BLOOD INST. OPIOID CRISIS ADDS TO PAIN OF SICKLE CELL PATIENTS (Sept. 15, 2017), https://www.nhlbi.nih.gov/news/2017/opioid-crisis-adds-pain-sickle-cell-patients; U.S. NAT'L CANCER INST., PDQ SUPPORTIVE AND PALLIATIVE CARE EDITORIAL BOARD, PDQ CANCER INFORMATION SUMMARIES (Mar. 6, 2019), https://www.cancer.gov/publications/pdq/information-summaries; U.S. NAT'L CANCER INST., PAIN IN PEOPLE WITH CANCER (Oct. 29, 2020), https://www.cancer.gov/about-cancer/treatment/side-effects/pain; AMERICAN CANCER SOCIETY, OPIOIDS FOR CANCER PAIN (Jan. 3, 2019), https://www.cancer.org/treatment/treatments-and-side-effects/physical-side-effects/pain/opioid-pain-medicines-for-cancer-pain.html.

[17] FDA, A GUIDE TO SAFE USE OF PAIN MEDICINE (Feb. 9, 2009), https://www.fda.gov/consumers/consumer-updates/guide-safe-use-pain-medicine (referencing a statement by the National Institutes of Health). *See also* JX-2177, State of New York Public Health Council, BREAKING DOWN THE BARRIERS TO EFFECTIVE PAIN MANAGEMENT: RECOMMENDATION TO IMPROVE THE ASSESSMENT AND TREATMENT OF PAIN IN NEW YORK STATE at 23 (Feb. 13, 1998) ("the public does not understand that opioid addiction when treating bona fide pain is rare").

medication and its risks.[18]

17. Since 1995, the FDA has struck that balance by approving—and continuing to approve—OxyContin as a Schedule II drug.[19]

18. The original FDA-approved OxyContin label and every updated OxyContin label since reflects the FDA's determination that OxyContin is safe and effective for the treatment of pain and has prominently warned that OxyContin is subject to abuse and diversion.[20]

19. Early versions of the FDA-approved OxyContin label reflected the FDA's view in 1996—consistent with the then-prevailing medical community's consensus[21]—that extended

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[18] *See* FDA, DEVELOPMENT & APPROVAL PROCESS – DRUGS (Oct. 28, 2019), https://www.fda.gov/drugs/development-approval-process-drugs#FDA ("FDA's Center for Drug Evaluation and Research (CDER) … ensures that drugs … work correctly and that their health benefits outweigh their known risks. … FDA approval of a drug means that data on the drug's effects have been reviewed by CDER, and the drug is determined to provide benefits that outweigh its known and potential risks for the intended population.").

[19] *See, e.g.*, JX-2097 (1995 Label) (PPLPC044000064536) at -537; JX-2121 (2019 Label) at 1, a*vailable at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022272s043lbl.pdf; JX-2122 (2021 Label) at 1, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022272s046lbl.pdf.

[20] *See, e.g.*, JX-2097 (1995 Label) (PPLPC044000064536) at -537 ("Oxycodone products are common targets for both drug abusers and drug addicts.... [C]are should be taken to prevent diversion or abuse by proper handling."); JX-2122 (2021 Label) at 1, 13, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022272s046lbl.pdf ("OXYCONTIN exposes users to risks of addiction, abuse and misuse, which can lead to overdose and death;" "Opioids are sought by drug abusers and people with addiction disorders and are subject to criminal diversion.").

[21] *See, e.g.*, JX-2215 (Harriet de Wit, et al., *Rate of Increase of Plasma Drug Level Influences Subjective Response in Humans*, PSYCHOPHARMACOLOGY (1992)) (PKY181753181) at -187 ("[P]harmacological agents and drug formulations with relatively slower onset would clearly have a lower potential for abuse than those with faster onset."); JX-2216 (William H. Oldendorf, *Some Relationships Between Addiction and Drug Delivery to the Brain*, NIDA RESEARCH MONOGRAPH (1992)) (PKY181870332) at -332 (observation that the "more immediate the effect after intake, the more addicting the substance is likely to be ...has been widely discussed in the literature and is not presented here as novel"); JX-2217 (Daniel Brookoff, *Abuse Potential of Various Opioid Medications*, 8 J. GEN. INTERN. MED. 688 (1993)) (PPLPC013000157356) at -359 ("This suggests

release opioids, like OxyContin, were less likely to be abused.[22]

20. Accordingly, OxyContin's original FDA-approved label stated: "Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug," and "Iatrogenic 'addiction' to opioids legitimately used in the management of pain is very rare."[23]

21. In 2001, however, "[r]eports of illegal misuse, abuse and diversion of OxyContin® … prompted" Purdue to, with the FDA's approval, revise OxyContin's label to add the black box warnings about the risks associated with OxyContin and to remove certain statements about the benefits of OxyContin, including that OxyContin was believed to reduce

that the controlled-release opioid formulations may have a lower potential for abuse than do other narcotic medications."); *id*. at -357 nn. 9 & 10 ("In some emergency departments, controlled-release formulations have become the analgesics of choice due to physicians' perceptions that they are rarely abused.").

[22] *See* FDA, TIMELINE OF SELECTED FDA ACTIVITIES & SIGNIFICANT EVENTS ADDRESSING OPIOID MISUSE & ABUSE, https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm338566.htm; JX-2180 (2/12/02 Transcript of Senate Hearing, Committee on Health, Education, Labor and Pensions) at 71 (As one FDA official testified before Congress in 2002: "[A]t the time of its approval, FDA believed the controlled-release characteristics of the OxyContin formulation would result in *less* abuse potential since, when taken properly, the drug would be absorbed slowly and there would not be an immediate 'rush' or high that would promote abuse.") (emphasis added).

[23] *See* JX-2097 (1995 Label) (PPLPC044000064536) -537. Prior FDA-approved labels for Percocet and Percodan—two non-Purdue Schedule II medicines containing oxycodone—contained similar statements in line with this consensus that, "Opioid addiction is relatively rare in patients with chronic pain but may be more common in individuals who have a past history of alcohol or substance abuse or dependence." *See* JX-2285 (Percodan Label 2010), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/007337s046lbl.pdf; JX-2228 (Percocet Label 2006), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/040330s015,040341s013,040434s003lbl.pdf.

abuse liability and that iatrogenic addiction to opioids is very rare.[24]

22. Since 2001, OxyContin's FDA-approved label has always prominently displayed a black-box warning describing the risks of addiction, abuse and fatal respiratory depression.[25]

23. As the FDA has explained: "A boxed warning is the most serious warning placed in the labeling of a prescription medication."[26]

24. In 2010, when Purdue launched the abuse-deterrent formulation ("**ADF**") of OxyContin designed to "[m]ake OxyContin less abusable, less desirable for abusers, and decrease diversion events,"[27] the FDA-approved label did not describe its abuse-deterrent properties because the FDA asked Purdue to conduct further studies.[28]

25. Those studies, which were reported to the PPI Board, showed that abuse and diversion fell substantially after OxyContin's reformulation.

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[24] JX-2220 (7/18/01 Purdue Dear HCP Letter) (PDD1715240425) at -425; *see also* U.S. Gen. Accounting Office., PRESCRIPTION DRUGS; OXYCONTIN ABUSE AND DIVERSION AND EFFORTS TO ADDRESS THE PROBLEM (Dec. 2003), https://www.gao.gov/assets/gao-04-110.pdf (describing 2001 label changes); JX-2103 (2001 Label) (PDD1501070063).

[25] *See. e.g.*, JX-2103 (2001 Label) (PDD1501070063) at -069; JX-2105 (Apr. 2010 Label), https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022272s006lbl.pdf; JX-2122 (2021 Label), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022272s046lbl.pdf.

[26] JX-2182 (9/9/08 FDA Letter to Connecticut Attorney General) at 2 (rejecting request by Connecticut Attorney General to add to the warnings on OxyContin's label).

[27] JX-2334 (6/12/12 Email attaching Update on Purdue's Post-Marketing Epidemiology Studies of Re-formulated OxyContin's Effects) (PPLPC057000011188) at -194.

[28] JX-2107 (Nov. 2010 Label), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022272s006lbl.pdf; JX-2283 (4/5/10 FDA News Release, *FDA approves New Formulation for OxyContin*), https://wayback.archive-it.org/7993/20170112130258/http:/www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm207480.htm (stating that Purdue "will be required to conduct a postmarket study to collect data on the extent to which the new formulation reduces abuse and misuse of this opioid.").

- For example, a June 18, 2012 presentation to the Board reported a 60% reduction in abuse of OxyContin following reformulation, according to one measurement.[29]
- A March 21, 2013 presentation to the Board reported similar results.[30]
- Studies showed that diversion of OxyContin similarly fell dramatically.[31]

26. The Board considered all of this a major success—proof that ADF OxyContin was accomplishing its goals.[32]

27. The FDA has revisited the OxyContin label more than 40 times—including when ADF OxyContin launched in 2010[33] and, most recently, on March 2, 2021[34]—and each time it has determined that OxyContin is safe and effective for its indicated uses in accordance with the full prescribing information.

28. The FDA's continued approval of OxyContin effectively rejects earlier studies on which many of the Non-Estate Claims rely to argue that the FDA or the courts should impose

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[29] *See* JX-2334 (6/12/12 Email attaching Update on Purdue's Post-Marketing Epidemiology Studies of Re-formulated OxyContin's Effects) (PPLPC057000011188) at -194.

[30] *See* JX-2074 (3/21/13 Abuse Deterrent Strategy Presentation) (PPLPC044000041897) at -961 (reporting a greater than 30% reduction in reported "Intentional Abuse Exposures"), -964 (reporting a greater than 60% reduction in OxyContin diversion events).

[31] *See, e.g.*, JX-2334 (6/18/12 Presentation to Board) (PPLPC057000011188) at -194; JX-2321 (10/25/11 Attachment to Exec. Comm. Notes Sent to Board) (PPLPC042000024694); JX-2074 (3/21/13 Presentation to Board) (PPLPC044000041897).

[32] *See, e.g.*, JX-2074 (3/21/13 Presentation to Board) (PPLPC044000041897) at -961, -962, -968; JX-2075 (7/25/13 Presentation to Board) (PPLP004409781) at -860.

[33] *See* JX-2105 (Apr. 2010 Label), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022272s006lbl.pdf.

[34] *See* JX-2122 (2021 Label), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022272s046lbl.pdf.

limits on the maximum dose or duration of treatment for opioid medications.[35]

29. The FDA,[36] the DEA,[37] and 42 State Attorneys General[38] have all recognized ADF OxyContin and/or ADF generally as a valuable step towards reducing the abuse of opioids.[39]

II. PURDUE'S HIGHLY PUBLICIZED 2007 GUILTY PLEA AND SETTLEMENTS RELEASED ALL PRE-2007 CLAIMS

A. The 2007 Federal Guilty Plea and Civil Settlement

30. In 2002, following press reports in 2001 concerning abuse of OxyContin,[40] the

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[35] *See, e.g.*, NYAG FAC ¶¶130–32 & nn. 44–50, ¶135 & nn. 52 & 53. *See also* JX-2359 (9/10/13 FDA Response to Letter from Physicians for Responsible Opioid Prescribing's ("**PROP**")) (PPLPC019000835061) at -065, -071–74 (letter from the FDA rejecting petition to impose a maximum dose or limit the duration of treatment).

[36] *See* FDA, ABUSE-DETERRENT OPIOID ANALGESICS, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/abuse-deterrent-opioid-analgesics ("The FDA is encouraging the development of prescription opioids with abuse-deterrent formulations (ADFs) to help combat the opioid crisis. The agency recognizes that abuse deterrent opioids are not abuse- or addiction-proof but are a step toward products that may help reduce abuse.").

[37] JX-2365 (9/17/13 Nat'l Ass'n of Attorneys Gen., J. Rannazzisi Tr., DEA (Presidential Initiative Current Issues In Drug Abuse Panel)) (PPLPC018000884102) ("Purdue did do us a major favor … I think that if we had more companies go to this delivery system … it will save lives.").

[38] JX-2385 (12/16/13 Letter from Nat'l Ass'n of Attorneys Gen. to FDA) (PPLPC046000057423) ("The State Attorneys General want to thank you for your recent efforts to ensure branded opioid drugs have abuse deterrent formulations.").

[39] In April 2013, the FDA approved a revised label stating that ADF OxyContin "has physicochemical properties expected to make abuse via injection difficult" and "to reduce abuse via the intranasal route," although abuse "by the oral route is still possible." JX-2114 (2013 label) (PPLPC003000060503).

[40] *See, e.g.*, JX-2147 (Timothy Roche, *The Potent Perils of a Miracle Drug*, TIME (Dec. 31, 2000), http://content.time.com/time/magazine/article/0,9171,93319,00.html) ("police say OxyContin abuse is an 'epidemic'"); JX-2148 (*Pain in the Asset*, FORBES (Feb. 5, 2001), https://www.forbes.com/forbes/2001/0205/057.html#785f28b3662d) ("OxyContin has become popular with drug abusers … . [T]he opioid produces a heroin-like high when snorted or injected. … Addiction is fast and overdoses are easy."); JX-2149 (Francis X. Clines & Barry Meier, *Cancer Painkillers Pose New Abuse Threat*, N.Y. TIMES (Feb. 9, 2001),

U.S. Attorney's Office for the Western District of Virginia began an investigation into Purdue's sales and marketing practices relating to OxyContin.[41]

31. In 2007, The Purdue Frederick Company, Inc. ("**Purdue Frederick**") pled guilty to felony misbranding of OxyContin (the "**2007 Guilty Plea**"), three Purdue Frederick executives pled guilty to strict liability misdemeanor misbranding charges, and Purdue Frederick settled related civil claims (the "**2007 Federal Settlement**").

32. Although the federal investigation lasted five years and examined the conduct of Purdue and its executives—including the Former Directors—from late 1995 to May 2007—the misconduct charged and admitted in the 2007 Guilty Plea ended on or about June 30, 2001.[42]

33. No Sackler Family Members were named, much less charged, in connection with any misconduct.[43]

34. In the Agreed Statement of Facts accompanying the 2007 Guilty Plea, Purdue admitted that until on or about June 30, 2001 "certain Purdue supervisors and employees, with the intent to defraud or mislead" healthcare professionals committed multiple acts of deception and misconduct in connection with OxyContin marketing.[44]

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https://www.nytimes.com/2001/02/09/us/cancer-painkillers-pose-new-abuse-threat.html) ("Illicit dealers have used suffering patients as well as fakers, the authorities report, to 'doctor shop' to obtain the drug, OxyContin, for resale. Addicts favor the drug because they have learned to circumvent its slow time-released protection and achieve a sudden, powerful morphine-like high.").

[41] JX-2164 (Laurence Hammack & Jen McCaffery, *OxyContin's Maker under Investigation in Southwest Virginia*, ROANOKE TIMES, June 13, 2005).

[42] *See* Information, Attachment B at ¶20, *United States v. The Purdue Frederick Co.*, 1:07-cr-0029 (W.D. Va. May 10, 2007), ECF No. 5-2 ("**2007 Agreed Statement of Facts**").

[43] *See id*.

[44] *Id.* ¶20 (capitalization deleted). *See also id.* at ¶¶21–43 (elaborating fraudulent conduct).

35. Purdue entered into a five-year Corporate Integrity Agreement ("**CIA**") with the Office of Inspector General ("**OIG**") of the U.S. Department of Health and Human Services ("**HHS**").[45]

36. The CIA was designed to assure Purdue's compliance with federal healthcare law, including all statutes, regulations and written directives of the FDA, Medicare, Medicaid and all other federal healthcare programs.[46]

37. The CIA obliged Purdue, *inter alia*, to (i) appoint a Compliance Officer to "be responsible for monitoring the day-to-day compliance activities engaged in by Purdue" and to make quarterly reports to the Board, and (ii) appoint a Corporate Compliance Council composed of the Compliance Officer and members of senior management charged with "support[ing] the Compliance Officer in fulfilling his/her responsibilities (*e.g.*, shall assist in the analysis of the organization's risk area and shall oversee monitoring of internal and external audits and investigations)."[47]

38. The CIA also required that Purdue (1) establish policies to ensure that (a) the promotion of Purdue's products met all applicable FDA and federal healthcare program requirements and (b) design its compensation practices "to ensure that financial incentives do not inappropriately motivate [Relevant Covered Persons] to engage in the improper promotion or

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[45] *See* Information, Attachment E, *United States v. The Purdue Frederick Co.*, 1:07-cr-0029 (W.D. Va. May 10, 2007), ECF No. 5-5 ("**CIA**").

[46] CIA §I, first paragraph.

[47] *Id*. at 4–5. The CIA recognized that Purdue already had the Compliance Officer and Compliance Council in place, as well as many other compliance initiatives, including a Code of Business Conduct, written policies and procedures, education and training programs, and review and disciplinary procedures. *See* CIA §I, second paragraph.

sales of Purdue's products;" (2) monitor sales representatives' interactions with prescribers in specified ways; and (3) engage an Independent Review Organization ("**IRO**") to assess and evaluate Purdue systems, processes, policies, and procedures relating to sales, marketing, and promotion of OxyContin.[48]

39. Purdue also undertook extensive reporting obligations to OIG.[49]

40. As part of the 2007 Federal Settlement, the United States released Sackler Family Members from all civil and criminal liability arising out of Purdue's sale and marketing of OxyContin prior to May 10, 2007.

41. In the accompanying 2007 Civil Settlement Agreement, the United States released "Purdue and its current and former directors, officers, employees, affiliates, owners, predecessors, successors and assigns" from any civil or administrative claim under any statute creating causes of action for civil damages or penalties, or common law, or equitable or disgorgement theories for conduct related to the marketing of OxyContin.[50]

42. In the 2007 Guilty Plea, the United States released claims for violations of law prior to May 10, 2007, pertaining to OxyContin "against the following, or any property owned by any of the following: Purdue, its current and former directors, officers, employees, ... owners (including trustees and trust beneficiaries of such owners) ...; any of Purdue's related and associated entities … and such related and associated entities' current and former directors, officers, employees, owners (including trustees and trust beneficiaries of such owners), ... and

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48 *Id.* at 6–16 and Appendix B, §I.

49 *Id.* at 25–31.

50 *See* Information, Attachment D at ¶2, *United States v. The Purdue Frederick Co.*, 1:07-cr-0029 (W.D. Va. May 10, 2007), ECF No. 5-4 ("**2007 Civil Settlement Agreement**").

trusts for the benefit of the families of the current and former directors of Purdue, including the trustees and beneficiaries of such trusts."[51]

B. The 27 2007 State Consent Judgments

43. In mid-2007, Purdue also entered into Consent Judgments ("**2007 State Consent Judgments**") with 26 states and the District of Columbia ("**Consent Judgment States**") settling claims related to "Purdue's promotional and marketing practices regarding OxyContin."[52]

44. Purdue paid $19.5 million[53] and agreed to follow a detailed set of "compliance provisions" requiring that Purdue:

- Not "market or promote OxyContin in a manner that is, directly or indirectly, inconsistent with the … Package Insert [FDA-approved label]"[54] or "make misrepresentations with respect to OxyContin's potential for abuse, addiction, or physical dependence as set forth in the Package Insert."[55]

- Establish, implement and follow, for 10 years, an OxyContin Abuse and Diversion Detection Program ("**ADD Program**") designed to identify potential abuse and diversion of OxyContin, requiring Purdue employees and sales representatives to report to the Office of the General Counsel observations such as, *inter alia*, "a) an apparent pattern of an excessive number of patients for the practice type …; b) an atypical pattern of prescribing techniques or locations …; c) information from a highly credible source or several sources (e.g., pharmacists, law enforcement or other health care workers) that a Health Care Professional or their patients are

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[51] *See* Plea Agreement at ¶11, *United States v. The Purdue Frederick Co.*, 1:07-cr-0029 (W.D. Va. May 10, 2007), ECF No. 6 ("**2007 Plea Agreement**").

[52] The Consent Judgment States are Arizona, Arkansas, California, Connecticut, the District of Columbia, Idaho, Illinois, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Montana, Nebraska, Nevada, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington, and Wisconsin. *See* JX-1900 (Consent Judgment at 1 and ¶1.M, *In re Purdue Pharma L.P.*, No. 07-C-00740 (Ky. Cir. Ct., Franklin Cnty. May 8, 2007)) ("**Ky. Consent Judgment**") (PPLPC051000121037).

[53] *See* Ky. Consent Judgment at ¶25.

[54] *Id.* at ¶3.

[55] *Id*. at ¶5.

abusing or diverting medications ….”[56]

- “[C]onduct an internal inquiry” of such reports and “take such further steps as may be appropriate based on the facts and circumstances.”[57]
- Not provide incentive bonus credits for sales “earned for a Health Care Professional who has been identified through the OxyContin Abuse and Diversion Detection Program as one upon whom sales representatives should not call” and not compensate sales professionals “based exclusively on the volume of OxyContin sales.”[58]
- Provide the states annually for three years statistics on “the number of reports, the number of investigations, and a summary of the results, including the number of ‘Do Not Call’ determinations,” with the caveat that the reports “shall not include the names of any specific Health Care Professionals,” and provide additional state-specific information to the Attorney Generals “upon written request.”[59]

45. Each of the 27 Consent Judgment States “release[d] and forever discharge[d], to the fullest extent permitted by law, Purdue and its past and present officers, directors, shareholders, employees, ... affiliates, [and] parents … of and from any and all civil causes of action, claims, damages, costs, attorney’s fees, or penalties that the Attorney General could have asserted ... under the State Consumer Protection Law by reason of any conduct that has occurred at any time” based on Purdue’s promotional and marketing practices regarding OxyContin.[60]

C. <u>49 State Medicaid Settlements</u>

46. In 2007, Purdue also settled with 48 states and the District of Columbia (the

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[56] *Id*. at ¶13. The ADD Program, which predated the 2007 Consent Judgments, was previously known by its governing Standard Operating Procedure (“**SOP**”)—SOP 1.7.1—which was instituted in November 2002. *See* JX-1864 (11/1/02 ADD SOP 1.7.1) (PPLP003430434).

[57] Ky. Consent Judgment at ¶13

[58] *Id*. at ¶17.

[59] *Id*. at ¶24.

[60] *Id*. at ¶35.

"**Medicaid Settlement States**")[61] all Medicaid claims based on allegations that Purdue "marketed OxyContin as less subject to abuse, illicit use and diversion and as less addictive and less likely to cause tolerance and withdrawal than other pain medications."[62]

47. Each settling state executed a settlement agreement that resolved claims for damage to the settling state's Medicaid program. In its settlement agreement, each settling state, "on behalf of itself, its officers, agents, agencies and departments," released Purdue "and its current and former directors, officers, employees, affiliates, owners, predecessors, successors and assigns" from any "civil or administrative monetary claim that the State has or may have for any claim submitted or caused to be submitted to the State Medicaid Program" related to the marketing of OxyContin.[63]

48. The 49 Medicaid Settlement States reserved, and did not release, nine separate categories of claims, including "any civil or administrative liability that the Company has or may

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[61] The Medicaid Settlement States included every State except (1) Kentucky, which was party to the 2007 State Consent Judgments and, later, another 2015 settlement with Purdue (*see* JX-2430 (12/15/15 settlement between Purdue and Kentucky) (PPLPUCC000701839), and West Virginia, which had already settled with Purdue pursuant to a December 14, 2004 agreement releasing "all claims of whatsoever kind or nature relating to OxyContin Tablets" against Purdue and its "present, former, or future ... principals, agents, ... officers, directors, shareholders, owners, employees, attorneys, representatives, subsidiaries, divisions, affiliates, associated companies, holding companies, partnerships, and joint ventures." *See* JX-2225 (12/15/04 Settlement Agreement and Release, *State of West Virginia v. Purdue Pharma, L.P.*, No. 01-CV-137 (W. Va. Cir. Ct., McDowell Cnty.) (VF 00932234).

[62] *See* Information, Attachment M at ¶II.D, *United States v. The Purdue Frederick Co.*, 1:07-cr-0029 (W.D. Va. May 10, 2007), ECF No. 5-14 ("**Form of State Settlement and Release**"). These settlements were contemplated by Purdue's 2007 Guilty Plea, which provided for the payment of dedicated settlement funds to compensate each state that elected to settle its related civil claims against Purdue and annexed a model form of settlement and release for the participating states to use. *See id*. and 2007 Guilty Plea at ¶3.b(2).

[63] *See* Form of State Settlement and Release at ¶III.2. All 27 Consent Judgments follow this form.

have under any state statute, regulation, or rule not covered by the release."[64] In return, Purdue agreed to "cooperate with and furnish to the State non-privileged documents and records in its possession relevant to a pending state investigation or matter."[65]

49. Purdue separately settled OxyContin-related claims with West Virginia in 2004 and Kentucky in 2015, and in both cases the States executed broad releases of OxyContin-related liability that extended to Sackler Family Members and entities.[66]

D. Purdue's 2007 Guilty Plea Was Widely Reported, and Purdue's Marketing of OxyContin Continued to be Scrutinized in the Press

50. Purdue's 2007 Federal Guilty Plea and associated admissions received extensive press and media coverage.

51. National publications like THE WALL STREET JOURNAL, THE NEW YORK TIMES, the LOS ANGELES TIMES, U.S. NEWS & WORLD REPORT, THE WASHINGTON POST, and the CHICAGO TRIBUNE reported that Purdue and three executives pled guilty to "criminal charges that they misled regulators, doctors and patients about the drug's risk of addiction and its potential to

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[64] *Id*. at ¶III.3.

[65] *Id*. at ¶III.6.

[66] Kentucky reached a litigation settlement with Purdue on December 18, 2015, in which Kentucky released Purdue and Sackler Family Members and entities for "all conduct … relating to any Purdue Opioid … including but not limited to conduct relating to ... the purchase, use, misuse, abuse, theft, prescription, marketing, manufacture, distribution, sale, promotion … and/or ingestion of any Purdue Opioid." JX-2430 (12/18/15 settlement between Purdue and Kentucky) (PPLPUCC000701839) at -141. And in 2004, PPLP, PPI and Purdue Frederick (together with Abbott Laboratories, which marketed OxyContin for a period of time) settled OxyContin-related claims with the State of West Virginia and received releases "of any and all claims of whatsoever kind or nature relating to OxyContin® Tablets," which similarly extended to Sackler Family Members and entities. JX-2225 (Dec. 15, 2004 Settlement Agreement and Release, *State of West Virginia v. Purdue Pharma, L.P.*, No. 01-CV-137 (W. Va. Cir., Ct. McDowell Cnty.) (VF 00932234)).

be abused" and detailed misleading statements that Purdue admitted in the plea.[67]

52. The national media carried stories.[68]

53. So, too, did international, local and regional publications.[69]

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[67] *See, e.g.*, JX-2153 (Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, THE N.Y. TIMES (May 10, 2007), https://www.nytimes.com/2007/05/10/business/11drug-web.html) (reporting that Purdue falsely contended that OxyContin "posed a lower threat of abuse and addiction to patients than do traditional, shorter-acting painkillers like Percocet or Vicodin" and "had fewer narcotic side effects"). *See also* JX-2162 (Heather Won Tesoriero, *OxyContin Maker Pleads Guilty*, WALL ST. J. (May 11, 2007), https://www.wsj.com/articles/SB117880640850298612); Martin Zimmerman, *Firm Admits Deceit About Painkillers*, L.A. TIMES (May 11, 2007), 2007 WLNR 8933448; *Narcotic Maker Guilty of Deceit*, U.S. NEWS & WORLD REPORT (May 21, 2007), 2007 WLNR 14230791 ("Purdue … and top current and former executives pleaded guilty last week … to charges of misbranding the prescription drug OxyContin between 1996 and mid-2001 as being less addictive than other painkillers."); *'Highly Abusable' drug OxyContin Maker Admits It Misled Public about Addition Risk*, CHI. TRIB. (May 11, 2007), 2007 WLNR 9017119; Carrie Johnson, *OxyContin Makers Admit Deception Addiction Danger from Painkiller Was Understated*, WASH. POST (May 11, 2007), 2007 WLNR 28530861 ("The manufacturer of the potent painkiller OxyContin … pleaded guilty to falsely marketing the drug in a way that played down its addictive properties and caused scores of people to become addicted.").

[68] *See, e.g.*, *World News With Charles Gibson*, ABC WORLD NEWS TONIGHT (May 11, 2007), 2007 WLNR 8906768 ("Today, the makers of OxyContin, the Purdue Pharma Company, admitted in court they knew the dangers of addiction, too, but lied about it to doctors and patients in order to encourage sales."); *Good Morning America*, ABC GOOD MORNING AMERICA (July 21, 2007), 2007 WLNR 14013033 ("A federal judge ordered Purdue Pharma and three top executives to pay more than $634 million for lying to doctors and the public about how addictive the drug really is."); Kathy Lohr, *OxyContin Hearing Prompts Tearful Testimony*, NPR WEEKEND EDITION (July 21, 2007), https://www.npr.org/templates/story/story.php?storyId=12144945 ("Purdue Pharma and three company executives pleaded guilty to misbranding OxyContin. That is they marketed it to doctors but failed to tell them of the dangers of the drug, it's high potential for abuse and addiction."); *Purdue Settles OxyContin Charge for $600M*, CNN MONEY (May 10, 2007), https://money.cnn.com/2007/05/10/news/companies/oxycontin/index.htm; *OxyContin Maker to pay $19.5M Settlement*, CNN MONEY (May 8, 2007), https://money.cnn.com/2007/05/08/news/companies/oxycontin/index.htm.

[69] *See, e.g.*, Barry Meier, *Admission of 'Misbranding' by Maker of OxyContin*, INT'L HERALD TRIB. (May 12, 2007), 2007 WLNR 9052024 ("The company and three of its current and former executives pleaded guilty … to criminal charges that the firm had misled doctors and patients when it claimed that the drug was less likely to be abused than traditional narcotics."); AP, *OxyContin Officials Plead Guilty to Misleading Public about Drug*, GRAND RAPIDS PRESS (May 11, 2007), 2007 WLNR 9100962; Alexander Soule, *Oxy's Dark Side Brings Pain: $635M Fine, Guilty Pleas*,

54. After 2007, OxyContin, its potential for abuse and addiction, and Purdue's marketing practices continued to receive extensive media attention.[70]

55. All Persons have been on actual or constructive notice of admitted or alleged Purdue misconduct with respect to OxyContin since at least May 2007.

FAIRFIELD CNTY. BUS. J. (May 21, 2007), 2007 WLNR 30055529 ("Purdue Pharma allowed sales staff to market the drug as less addictive than other painkillers after receiving reports of abuse and black market activities."); Dr. Michael Wilkes, *A True Tale of (Corporate) Drug Abuse*, SACRAMENTO BEE (May 19, 2007), 2007 WLNR 9424763 ("Purdue Frederick heavily promoted [OxyContin] in a false and misleading manner, attempting to convince doctors that it was not addictive and could be used for less-serious pain."); Laurence Hammack, *OxyContin Settlement A Reversal of Fortune*, ROANOKE TIMES (May 12, 2007), 2007 WLNR 9140815 ("Along with the company's president and its former medical director, Udell pleaded guilty to his role in a marketing blitz that hyped OxyContin's strengths while downplaying a key weakness: its propensity for abuse and addiction."); *3 Executives Admit Hiding OxyContin Risks*, ALBANY TIMES UNION (May 11, 2007), 2007 WLNR 8973246 ("The company that makes the narcotic painkiller OxyContin … pleaded guilty … to criminal charges that they misled regulators, doctors and patients about the drug's risk of addiction and its potential to be abused."); Sue Lindsey, *Executives Plead Guilty to Misleading Public, Company, Officers Will Pay $634.5 Million in Fines in OxyContin Case*, CHARLESTON DAILY MAIL (May 11, 2007), 2007 WLNR 8983543; Barry Meier, *Guilty Pleas in OxyContin 'Misbranding' / Drug Maker, 3 Executives Are Fined Millions for Deceptive Claims*, HOUS. CHRONICLE (May 11, 2007), 2007 WLNR 8978627.

[70] *See, e.g.*, *Kentucky Counties Sue Makers of "Hillbilly Heroin,"* REUTERS (Oct. 4, 2007), https://www.reuters.com/article/us-painkiller-kentucky-lawsuit/kentucky-counties-sue-makers-of-hillbilly-heroin-idUSN0436554420071004 (reporting suit by Kentucky counties against "the makers of the potent painkilling drug OxyContin, charging that abusers of 'hillbilly heroin' have filled state jails and treatment centers"); *Hold Pharma Accountable for Addiction Epidemic*, THE PATRIOT LEDGER (Dec. 15, 2011), 2011 WLNR 26039005 ("[T]he true culprit behind this pandemic was and is still today the manufacturer Purdue Pharma, the maker of OxyContin and the source that ignited a pandemic of addiction."); *Prescription for Tragedy / Part One of Two; Feeding the Epidemic*, COURIER-J. (June 3, 2012), 2012 WLNR 12113448 ("[M]any medical and addiction experts say well-meaning doctors are feeding the epidemic by prescribing narcotics for too many conditions, encouraged by years of aggressive marketing by drug companies such as Purdue Pharma, the manufacturer of OxyContin…."); Peter Whoriskey, *The Prescription Painkiller Binge*, WASH. POST (Dec. 31, 2012), 2012 WLNR 28197401 (reporting that claims that prescription opioids had minimal risk of addiction were "developed in studies supported by Purdue," were "unsupported by the data," or "undercounted patients reporting withdrawal symptoms"); Scott Glover & Lisa Girion, *OxyContin Maker Closely Guards Its List of Suspect Doctors*, L.A. TIMES (Aug. 11, 2013), 2013 WLNR 19811609.

III. THE FORMER DIRECTORS MONITORED A COMPREHENSIVE COMPLIANCE PROGRAM AT PURDUE THROUGHOUT THE RELEVANT PERIOD

56. The predicate of most of the Non-Estate Claims against the Former Directors is that they knew that Purdue was deceptively marketing OxyContin or were negligent in not preventing diversion of OxyContin.

57. During the Relevant Period, the members of the Raymond Sackler Family ("**Side B**") who served as directors of PPI held no position at PPI other than their positions as directors, and none had any position at PPLP at all.[71]

58. The undisputed record categorically establishes that, from June 1, 2007 (after Purdue entered into the 2007 Guilty Plea, the Federal Settlement, and the 2007 State Consent Judgments) and through the time that the last Side B director left the PPI Board in December 2018[72] (the "**Relevant Period**"), the Former Directors had a good faith and reasonable understanding, based on extensive reports from Purdue management, that Purdue's opioid marketing (which ended in February 2018[73]) was being conducted in compliance with law and that Purdue was implementing its anti-diversion programs.

59. As detailed below, the Board implemented and monitored a comprehensive compliance infrastructure at Purdue and received detailed quarterly compliance reports from

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[71] *See* JX-2093 (Purdue's Responses and Objections to Plaintiff's First Set of Interrogatories, *People of the State of New York v. Purdue Pharma L.P., et al.*, No. 400016/2018 (N.Y. Sup. Ct., Suffolk Cnty. Dec. 20, 2018).

[72] Beverly Sackler left the PPI Board on October 14, 2017; Richard Sackler left the Board on July 24, 2018; David Sackler left the Board on August 14, 2018, and Jonathan Sackler left the Board on December 8, 2018. *See* JX-2090 (Purdue Directors List) (PPLPUCC500140094).

[73] *See* Purdue Pharma L.P. Issues Statement on Opioid Promotion (Feb. 9, 2018), https://www.purduepharma.com/news/2018/02/09/purdue-pharma-l-p-issues-statement-on-opioid-promotion/.

management documenting and certifying that Purdue was operating in compliance with law throughout the Relevant Period:[74]

a. For the period from July 31, 2007 through July 30, 2012,[75] the Board was also informed that OIG and IRO monitors confirmed that Purdue was operating in compliance with its Corporate Integrity Agreement, which had been

[74] *See* JX-2654 (Oct. 31, 2007 Quarterly Compliance Report) (PPLPC019000172297); JX-1828 (Feb. 8, 2008 Quarterly Compliance Report) (PPLPC019000195607); JX-1829 (1Q 2008 Quarterly Compliance Report) (PPLP004401169); JX-2655 (2Q 2008 Quarterly Compliance Report) (PPLP004401342); JX-2656 (3Q 2008 Quarterly Compliance Report) (PPLP004402032); JX-2657 (4Q 2008 Quarterly Compliance Report) (PPLP004402205); JX-2658 (1Q 2009 Quarterly Compliance Report) (PPLP004402651); JX-2659 (2Q 2009 Quarterly Compliance Report) (PPLPC012000236639); JX-2660 (3Q 2009 Quarterly Compliance Report) (PPLP004402982); JX-2661 (4Q 2009 Quarterly Compliance Report) (PPLP004403707); JX-2662 (1Q 2010 Quarterly Compliance Report) (PPLP004404102); JX-2663 (2Q 2010 Quarterly Compliance Report) (PPLP004404551); JX-2664 (3Q 2010 Quarterly Compliance Report) (PPLP004405460); JX-2665 (4Q 2010 Quarterly Compliance Report) (PPLP004405709); JX-2666 (1Q 2011 Quarterly Compliance Report) (PPLP004406032); JX-2667 (2Q 2011 Quarterly Compliance Report) (PPLP004406466); JX-2668 (3Q 2011 Quarterly Compliance Report) (PPLP004406790); JX-2669 (4Q 2011 Quarterly Compliance Report) (PPLP004407554); JX-2670 (1Q 2012 Quarterly Compliance Report) (PPLP004407950); JX-1830 (Jul. 19, 2012 Quarterly Compliance Report) (PPLPUCC9002892662); JX-2672 (3Q 2012 Quarterly Compliance Report) (PPLP004408439); JX-2673 (4Q 2012 Quarterly Compliance Report) (PPLP004409357); JX-2674 (1Q 2013 Quarterly Compliance Report) (PPLP004409694); JX-1831 (Jul. 25, 2013 Quarterly Compliance Report) (PPLP004409783); JX-2675 (3Q 2013 Quarterly Compliance Report) (PPLP004410506); JX-2676 (4Q 2013 Quarterly Compliance Report) (PPLP004410797); JX-2677 (1Q 2014 Quarterly Compliance Report) (PPLP004411166); JX-2678 (2Q 2014 Quarterly Compliance Report) (PPLP004411277); JX-2679 (4Q 2014 Quarterly Compliance Report) (PPLP004411811); JX-2680 (1Q 2015 Quarterly Compliance Report) (PPLP004412071); JX-2681 (2Q 2015 Quarterly Compliance Report) (PPLP004412152); JX-2682 (3Q 2015 Quarterly Compliance Report) (PPLP004412546); JX-1832 (4Q 2015 Quarterly Compliance Report) (PPLPC063000018836); JX-1833 (Aug. 25, 2016 Quarterly Compliance Report) (PPLPUCC003271544); JX-2683 (3Q 2016 Quarterly Compliance Report) (PPLPUCC9002790025); JX-1834 (Mar. 2017 Quarterly Compliance Report) (PPLP004413913); JX-2684 (Jun. 2017 Quarterly Compliance Report) (PPLP004414244); JX-2685 (Aug. 2017 Quarterly Compliance Report) (PPLPC021000899767); JX-2686 (3Q 2017 Quarterly Compliance Report) (PPLPC022001020792); JX-1835 (Dec. 2017 Quarterly Compliance Report) (PPLPC021000920798); JX-2687 (Mar. 2018 Quarterly Compliance Report) (PPLP004414931); JX-2688 (Aug. 10, 2018 Quarterly Compliance Report) (PPLP004415061).

[75] CIA at ¶II.A; Purdue 2007 Civil Settlement Agreement at ¶III.1; JX-2339 (IRO Report on Promotional and Product Services Transactions Engagement for Reporting Period 5) (PPLPC019000720508) at -509.

implemented to assure Purdue's compliance with federal healthcare law.

b. In July 2012, as the OIG monitorship was coming to an end, the Board was informed that PPLP had retained outside counsel to provide ongoing reviews of compliance program effectiveness. (JX-1830 (2Q 2012 Quarterly Compliance Report) (PPLPUCC9002892662) at slide 7.)

c. And the Board understood that Purdue maintained and enhanced its compliance program after the CIA ended, receiving detailed compliance reports from July 2012 through 2018 documenting that.

A. The Board Monitored a Rigorous Compliance Infrastructure at Purdue

1. The 2005 and 2007 Corporate Compliance Charters

60. In 2005—in the midst of the federal investigation that culminated two years later in Purdue's 2007 Guilty Pleas for conduct that ended on or about June 30, 2001—the Board adopted a "[s]tate-of-the-[a]rt" Compliance Charter (the "**2005 Compliance Charter**") requiring a strict compliance regimen at Purdue.[76]

61. The 2005 Corporate Compliance Charter established a "formal Board mandate covering Purdue's commitment to an ethical corporate culture and a compliance program."[77]

62. It required that the Vice President of Corporate Compliance implement a program satisfying each of the seven elements of an "Effective Compliance Program" as defined

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[76] JX-1830 (2Q 2012 Quarterly Compliance Report) at Slide 11. *See also* JX-2012 (2005 Corporate Compliance Charter) (PKY183307471) (Purdue's [redacted]); JX-2661 (2009 Q4 Quarterly Compliance Report) (PPLP004403707) at -722 (describing Purdue's compliance program as "ahead of the curve").

[77] JX-2227 (9/20/05 Email from B. Weinstein to Board) (PPLPC036000062443); JX-2012 (2005 Corporate Compliance Charter) (PKY183307471) ("it was unanimously decided … that the Corporation be and it hereby is authorized and directed to approve for itself and on behalf of the Partnership and its wholly owned subsidiaries the Company Compliance Charter recognized under the Federal Sentencing Guidelines, the HHS Officer of the Inspector General and other Governmental bodies in the form attached hereto"); *id.* at -472.

by HHS OIG and the Sentencing Guidelines,[78] including:

- Formation and function of departmental compliance programs,
- Performance of on-going risk assessments,
- Development and implementation of training and education programs responsive to risks assessed, and tailored to the function and responsibility of the Companies' employees and other agents,
- Development of mechanisms for compliance monitoring and auditing, including a toll-free Ethics and Compliance Hotline for reporting anonymously without fear of retaliation,
- Maintenance of effective lines of internal communication,
- Maintenance of compliance-related performance and disciplinary standards,
- Conducting periodic reviews and updates to policies and procedures adopted by the Companies, and
- Development of mechanisms for response to violations of law or Company standards (including the handling of internal investigations).[79]

63. The Board also understood that Purdue's compliance program was audited by prominent outside law firms on two separate occasions, and that both of which positively appraised the compliance program.

64. First, in November 2005—before the 2007 Guilty Plea but after the misconduct had ended—the Board was informed that the Compliance Department had received a "[h]ighly

[78] The seven elements are: "1. Implementing written policies, procedures and standards of conduct. 2. Designating a compliance officer and compliance committee. 3. Conducting effective training and education. 4. Developing effective lines of communication. 5. Conducting internal monitoring and auditing. 6. Enforcing standards through well-publicized disciplinary guidelines. 7. Responding promptly to detected offenses and undertaking corrective action." *See* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, HEALTH CARE COMPLIANCE PROGRAM TIPS, https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf (last visited July 28, 2021).

[79] JX-2012 (2005 Corporate Compliance Charter) (PKY183307471) at -473–74.

favorable [outside counsel] audit" of Purdue's compliance program.[80]

65. Two years later, the Board revised the Corporate Compliance Charter to incorporate requirements of the Corporate Integrity Agreement with the federal government (the "**2007 Compliance Charter**").[81]

66. The 2007 Corporate Charter required the creation and maintenance of a Corporate Compliance Council to be chaired by the VP of Corporate Compliance[82] and including members from "[t]he Office of the General Counsel, Human Resources, Corporate Quality, Field Operations, Risk Management and Health Policy, Medical Research, Regulatory Affairs, and Finance."[83]

67. The Compliance Council was formed to "support the Vice President, Corporate Compliance in fulfilling his/her responsibilities with respect to Purdue's compliance program," including with respect to the "analysis of Purdue's compliance risk areas and oversight of compliance training, audits, and monitoring."[84]

2. From 2007-2018, the Board Received Detailed Quarterly Management Reports Confirming Purdue's Implementation of Compliance Charter and Compliance with Law

68. From mid-2007 on, the Board received detailed compliance reports from the Compliance Department on a quarterly basis.[85]

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80 JX-1836 (11/1/05 Update and Budget Report) (PPLPC018000070210) at slide 39.

81 JX-2013 (Decisions of the PPI Board) (PPLP004415283) at -289–90. *See id.* at -285–90.

82 *Id*. at -289–90.

83 *Id*.

84 *Id*.

85 *See* n.74, *supra*. *See also* JX-2003 (Feltz MDL Dep. Tr.) at 149:17–19 [redacted] Regular

69. The quarterly compliance reports documented the substantive efforts undertaken by Purdue to ensure the effective implementation of Purdue's Compliance Charter and compliance program, and they apprised the Board of any significant risks or compliance issues with respect to each element of Purdue's compliance program.[86]

70. As contemplated by the Compliance Charter, the quarterly compliance reports served as a primary mechanism through which the Board monitored Purdue's compliance program.

71. The Vice President of Corporate Compliance also made oral presentations to the Directors at Board meetings, where the substance of the quarterly reports was discussed.[87]

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compliance reports were also made to the Board even before mid-2007. *See, e.g.*, JX-1819 (Jan. 31, 2005 Report to the Board) (PPLPC013000125609) at -634; JX-1820 (April 15, 2005 Report to the Board) (PPLPC022000070889) at -929; JX-1821 (July 13, 2005 Compliance Report) (PPLPC026000024332); JX-1823 (April 5, 2006 Compliance Report) (PPLPC031000329746); JX-1824 (Nov. 2006 Compliance Report) (PPLPC031000329745); JX-1826 (April 24, 2007 Compliance Report) (PPLP004399705).

[86] *See, e.g.*, JX-2664 (3Q 2010 Quarterly Compliance Report) (PPLP004405460) (detailed presentation of compliance standards, procedures, personnel and oversight, training (in-house and in the field), 24-hour ethics hotline, diagrammatic analysis of current compliance matters).

[87] *See, e.g.*, JX-2013 (5/11/07 PPI Minutes) (PPLP004415283); JX-2014 (8/6/07 PPI Minutes) (PPLP004415309); JX-2016 (2/14/08 PPI Minutes) (PPLP004415351); JX-2020 (2/5/09 PPI Minutes) (PPLP004415482); JX-2022 (5/8/09 PPI Minutes) (PPLP004415535); JX-2023 (10/19/09 PPI Minutes) (PPLP004415611); JX-2027 (11/18/20–11/19/20 PPI Minutes) (PPLP004415771); JX-2029 (2/3/11 PPI Minutes) (PPLP004415797); JX-2031 (7/21/11 PPI Minutes) (PPLP004415826); JX-2033 (11/2/11 PPI Minutes) (PPLP004415835); JX-2034 (1/19/12 PPI Minutes) (PPLP004415845); JX-2037 (7/19/12 PPI Minutes) (PPLP004415869); *see* JX-2003 (Feltz MDL Dep. Tr.) at 149:24-150:2 [redacted]; JX-2008 (Cecil Pickett Dep. Tr.) at 118:2–4 [redacted]; *id.* at 132:2–133:3 [redacted]; JX-2015 (8/6/07 Roncalli Notes) (PPLPBN-00000107) (noting delivery of compliance report at board meeting); JX-2024 (10/19/09 Roncalli Notes) (PPLPBN-00000446) (same).

72. In addition to the written and oral quarterly compliance reports, the Board received lengthy quarterly reports from management that provided updates on each department of PPLP that included department-specific compliance efforts, as well as a separate discussion of the Corporate Compliance Department.[88]

73. The Board also received minutes from Executive Committee meetings and supporting documents, all of which showed that the members of the Executive Committee—Purdue leadership across departments—were focused on, and attended to, the implementation of Purdue's compliance program.[89]

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[88] *See, e.g.*, JX-2061 (4Q 2011 Board Report) (PPLPC012000362869) at -877, -887, -899, -905 (reporting sales force compliance objective was to "[o]perate within all established company policies, government laws and regulations and PhRMA guidelines to ensure complete compliance," "and there were "[n]o issues to report;" that "Totowa and Cranbury sites" were audited with "no observations or recommendations;" that IT was collaborating with Corporate Compliance "to manage all company related HCP spend in preparation for the Sunshine Act;" that "[t]he Fourth Annual Report under Purdue's Corporate Integrity Agreement was filed.… We received a limited number of clarifying questions … and answered them to [the OIG Monitor's] full satisfaction, with two minor follow up activities nearly completed."). *See also, e.g.*, JX-2056 (1Q 2010 Board Report) (PPLP004317547) at -559 ("By letter dated April 1st, Purdue's OIG Monitor confirmed that upon its review of Purdue's Second Annual Report (submitted September 2009) and supplemental information provided in response to OIG's request, Purdue was in compliance with the terms of its Corporate Integrity Agreement during the second reporting period"); *id.* at -565 ("Human Resources[:] ... Assure program and management compliance with all regulatory and legal requirements"); *id.* at -549 ("Marketing & Sales[:] ... Compliance with all relevant policies, government law and regulation will be closely monitored"); *id.* at -552 ("Manufacturing & Supply Chain[:] Assure compliance with all FDA, DEA OSHA and EPA laws and regulations"); JX-2705 (2Q 2011 Board Report) (PPLP004366913); JX-2064 (3Q 2012 Board Report) (PPLP004366816); JX-2693 (1Q 2013 Board Report) (PPLP004367540); JX-2068 (4Q 2013 Board Report) (PPLPC002000181035).

[89] *See, e.g.*, JX-2250 (1/24/08 email to Board with Executive Committee Minutes) (PPLPC041000006381) at -385 ("Human Resources Update" "Compensation Components[:] DL briefly reviewed the Business Success Scorecard being developed which will be used in determining the percentage of target amount to be paid for the Annual Bonus and Long-Term Results Program. The scorecard will take into consideration compliance...."); JX-2253 (3/8/08 email to Board with Executive Committee Minutes) (PPLPC044000015917) at -923 ("Bert Weinstein (BW) announced that a new OWL [Online Workplace Learning (training)] module to

3. The Board Monitored Implementation of the Compliance Program

74. The Board used the information it received, including the quarterly compliance reports, to monitor Purdue's implementation and ongoing satisfaction of each of the seven elements of an "effective compliance program" under OIG standards and the Sentencing Guidelines, as dictated by Purdue's Compliance Charter.[90]

a. The First Element: Compliance Standards

75. Under the OIG standards, the first element of an "effective compliance program" is "Implementing written policies, procedures and standards of conduct" (the "**First Element**").[91]

76. The Board was informed that Purdue implemented and maintained an "extensive system" of "policies and procedures" to promote employee awareness of the laws and standards

educate colleagues on Conflict of Interest will be announced shortly, and that the Totowa investigation has been resolved."); JX-2278 (9/30/09 email to Board with Executive Committee Minutes) (PPLPC049000029885) at -889–90 ("Bert Weinstein provided an update on the Massachusetts and Vermont restrictions on meals, which apply to all employees who are providing a meal to doctors...."); JX-2293 (11/24/10 email to Board with Executive Committee Minutes) (PPLPC012000299851) at -866 (Power Point presentation on new OIG guidance issued Oct. 20, 2010); JX-2313 (8/3/11 email to Board with Executive Committee Minutes and attached slides) (PPLPC012000337158) at -164, slide 7 (minutes report on 10-year plan, with related Power Point presentation emphasizing objectives to "[e]nsure that we achieve all of the above [goals] with an ongoing focus and commitment to compliance and quality"); JX-2336 (7/26/12 email to Board with Executive Committee Minutes and attachment) (PPLPC057000011447) at -458–68 (Power Point presentation on Purdue's "Post-CIA Compliance Program" reporting "***Post-CIA there will be little change in Purdue's compliance program***" (italics and bold in original) and comparing ongoing compliance program vs. CIA requirements in some detail).

[90] JX-2664 (3Q 2010 Quarterly Compliance Report) (PPLP004405460) at -465 ("Purdue's compliance program has also been implemented pursuant to the OIG Compliance Program Guidance for Pharmaceutical Manufacturers").

[91] *See* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, HEALTH CARE COMPLIANCE PROGRAM TIPS, https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf (last visited July 12, 2021).

applicable to interactions with healthcare professionals,[92] which demonstrates compliance with the First Element:

#1- Standards of Conduct & Procedures

- Purdue's "Code of Business Ethics" is distributed to all employees of Purdue and associated US companies (including new hires)
  - All employees receive annual training
  - All employees must annually certify that they have received, read, understood and agree to abide by the Code
  - Code is on Purdue's internet and intranet web sites, and in hardcopy
- The Code articulates our ethics and compliance expectations and promotes employee awareness of responsibilities under current law and Purdue policies, including the obligation to report known or suspected violations
- Purdue has healthcare policies and procedures to promote employee awareness of the laws and standards applicable to interactions with healthcare professionals and other customers in the conduct of our business
- We also have an extensive system of departmental SOPs and WPDs

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JX-2664 (3Q 2010 Quarterly Compliance Report) (PPLP004405460) at -468.

77. Many other Board reports address the same subject.[93]

[92] *See, e.g.*, JX-2664 (3Q 2010 Corporate Compliance Quarterly Report) (PPLP004405460) at -468. *See also* JX-1834 (Mar. 2017 Quarterly Compliance Report) (PPLP004413913) at -917, -919 (describing Purdue's satisfaction of all seven elements of an effective compliance program, including "Standards & Procedures" and enhancements); JX-2687 (Mar. 2018 Quarterly Compliance Report) (PPLP004414931) at -936 (describing Purdue's satisfaction of all seven elements of an effective compliance program; also providing "sample" of "Standards & Procedures" compliance activities).

[93] *See, e.g.*, JX-1827 (Aug. 8, 2007 Quarterly Compliance Report) (PPLP004399954) at -963–64 (identifying "Standards (e.g., Code, Policies/SOPs/WPDs)[:] Procedures for Code of Business Ethics[,] Distribution of Policies and Procedures per job functions[,] Selling and Marketing under FHCP requirements[,] Product Materials under FDA requirements[,] Compensation for RCPs who sell and promote[,] Off-Label information request referrals by reps[,] Info provided by Medical Services and Liaisons[,] Material and Product info provided by reps[,] Contractual arrangements (fee-for-service) with HCPs[,] Funding of activities and grants[,] Development and Production of 'Materials[,]' Discontinuation of Promotional 'Materials[,]' [and] Employee Discipline"); JX-1834 (Mar. 2017 Ethics & Compliance Report) (PPLP004413913) at -917, -919 (describing Purdue's satisfaction of all seven elements of an effective compliance program, including "Standards & Procedures" and enhancements); JX-2687 (Mar. 2018 Quarterly Compliance Report) (PPLP004414931) at -936 (describing Purdue's satisfaction of all seven elements of an

78. Purdue's healthcare policies, procedures and compliance standards included SOPs that strictly delineated how Purdue was allowed to market OxyContin.

79. For example, Purdue's procedures required the Medical Services, Regulatory Affairs, and Legal departments to review and approve all promotional literature before it could be used.[94]

80. Purdue's guidelines also required that "[a]ll product claims made verbally by" Purdue sales representatives must "be consistent with the product labeling and Company approved Materials," and expressly "prohibit[ed] the use of unapproved Materials to promote Purdue products at any time."[95]

81. They prohibited sales representatives from "draft[ing] and/or send[ing] correspondence to any Health Care Practitioner (HCP) that ha[d] not previously gone through the internal Material Review Process and received written approval for distribution," except in extremely limited circumstances unrelated to the promotion of Purdue products.[96]

82. The compliance reports informed the Board that Purdue's "compliance program [was] regularly updated."[97]

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effective compliance program; also providing "[s]ample" of "Standards & Procedures" compliance activities).

[94] *See* JX-1873 (Purdue SOP Num. GC-SOP-0020, Material Review Process) (POK003707782); *see also* JX-1886 (Purdue SOP Num. REG-SOP-0060, Material Approval Process) (PWA000000769).

[95] JX-2245 (Compliance Officer Certification) (PPLP004432090) at -091.

[96] *Id.* at -092.

[97] JX-2681 (2Q 2015 Quarterly Compliance Report) (PPLP004412152) at -163. *See also* JX-1834 (Mar. 2017 Quarterly Compliance Report) (PPLP004413913) at -917 (reporting on "routine updates" to "Standards & Procedures" and the "[d]evelopment of new policies & procedures").

83. For example, the Board monitored updates to Purdue's policies that (i) incorporated changes to regulatory guidance in the "Sentencing Guidelines, OIG's Compliance Guidelines, and CIAs;"[98] (ii) "[f]ormalize[d] the exact criteria consultants must meet to be eligible for each type of HCP consultancy;"[99] and (iii) addressed "[p]lanned updates anticipated to Code of Business Ethics and Healthcare Law Compliance (HCLC) Policies."[100]

b. The Second Element: Compliance Officer & Compliance Committees

84. Management confirmed to the Board that Purdue also satisfied the second element of an "effective compliance program:" "Designating a compliance officer and compliance committee" (the "**Second Element**").[101]

85. The Board knew that a compliance officer was in place: the VP of Corporate Compliance had been reporting to them for years, and he continued in that role thereafter.[102]

86. The Board was informed that the required Compliance Council had been established and included members from key departments throughout Purdue.[103]

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98 JX-2681 (2Q 2015 Quarterly Compliance Report) (PPLP004412152) at -163.

99 JX-1832 (4Q 2015 Quarterly Compliance Report) (PPLPC063000018836) at -839.

100 JX-1834 (Mar. 2017 Quarterly Compliance Report) (PPLP004413913) at -919.

101 *See* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, HEALTH CARE COMPLIANCE PROGRAM TIPS, https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf (last visited July 28, 2021).

102 *See, e.g.*, JX-2664 (3Q 2010 Quarterly Compliance Report) (PPLP004405460) at -469.

103 *See* JX-1827 (Aug. 8, 2007 Compliance Report) (PPLP004399954) at -960 (listing members of Purdue's Compliance Council); JX-1829 (1Q 2008 Quarterly Compliance Report) (PPLP004401169) at -173 (reporting that the Corporate Compliance Council was established and had met, identifying its members, and advising that in its quarterly meeting on April 22, 2008, it had "reviewed CIA status and milestones, ongoing investigations, audit planning, audits and monitoring programs, hotline and other matters.").

87. The Board was advised that the Council would "assist in [the] analysis of compliance risk areas, and monitor[the Company's] audits and investigations."[104]

88. The Board was also aware that additional compliance committees were empaneled,[105] and the quarterly compliance reports provided the Board with the information they needed to monitor these additional compliance committees and their functions.[106]

c. The Third Element: Training

89. Consistent with the third element of an "effective compliance program," "Conducting effective training and education" (the "**Third Element**"),[107] the quarterly compliance reports provided the requisite data for the Board to confirm that Purdue was training all new Company employees, and kept current employees up to date, on its policies as well as

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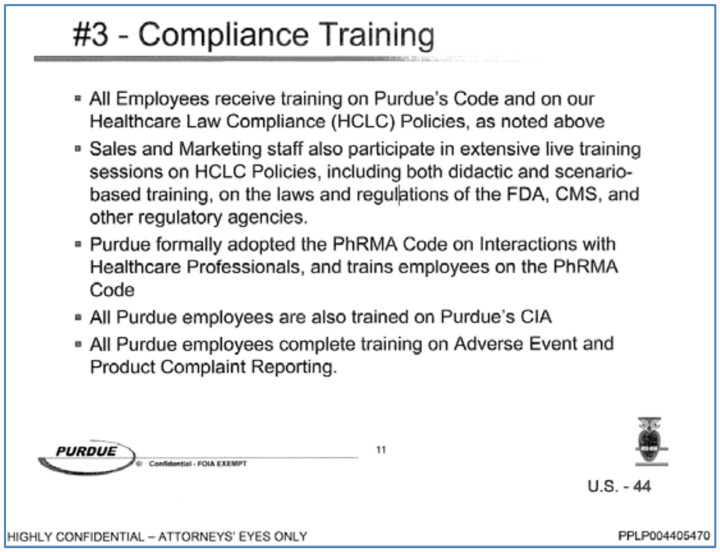
[104] JX-1829 (1Q 2008 Quarterly Compliance Report) (PPLP004401169) at -173.

[105] Purdue's compliance structure included the Corporate Compliance Council, the Sales and Marketing Compliance Committee, the Vice President's Compliance Council, the R&D Compliance, the Administrative Area Compliance Committee, the Grant Review Committees, the Reportable Event Committee, the Discipline Committee, the Quality Steering & Technical Operations Committee, the Executive Committee and the Board. *See* JX-2664 (3Q 2010 Quarterly Compliance Report) (PPLP004405460) at -497.

[106] *See, e.g.*, JX-1833 (Aug. 25, 2016 Quarterly Compliance Report) (PPLPUCC003271544) at -545 ("Ethics & Compliance, in consultation with the Law Department, is assuming ownership of several monitoring and investigation activities . . . . Ethics & Compliance is in the process of recasting the role of the senior executive Corporate Compliance Council to expand its scope to include enterprise-wide risk assessment on an ongoing basis."); JX-1834 (Mar. 2017 Quarterly Compliance Report) (PPLP004413913) at -919 (update on "Compliance Officer & Committees" reports: "Expansion for key roles – Suspicious Order Monitoring (SOM), Abuse and Diversion Detection (ADD); compliance champions;" and "Establishment of Enhanced Risk & Compliance Committee"); JX-2687 (Mar. 2018 Quarterly Compliance Report) (PPLP004414931) at -936 ("Updated membership of Commercial Ethics & Compliance Committee;" "Convened Medical Affairs Ethics & Compliance Committee;" "Anticipating first meeting of Enterprise Compliance & Risk Management Council").

[107] *See* U.S. DEP'T OF HEALTH AND HUMAN Services, HEALTH CARE COMPLIANCE PROGRAM TIPS, https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf (last visited July 28, 2021).

relevant laws, regulations, and the CIA:



JX-2664 (3Q 2010 Corporate Compliance Quarterly Report) (PPLP004405460) at -470.[108]

90. The Board was advised that Purdue provided additional live training to its employees throughout the year and offered on-demand training programs through its Online Workplace Learning platform,[109] and that the Compliance Department undertook ongoing "[e]fforts to continually assess educational gaps and provide targeted training."[110]

91. The VP of Corporate Compliance also informed the Board, and documented in compliance reports, that the "Purdue organization is well trained"[111] and that Purdue employees

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[108] *See also, e.g.*, JX-1833 (Aug. 25, 2016 Quarterly Compliance Report) (PPLPUCC003271544) at -547 ("In Q1, Ethics & Compliance … partnered with Sales Training to create supplemental training (Phase II) that was provided live to all Territory Business Managers hired in 2015-2016."); JX-1834 (Mar. 2017 Quarterly Compliance Report) (PPLP004413913) at -917 ("Innovative new live sales training introduced;" "27 OWL modules in 2016 – 100% completion rate").

[109] JX-2664 (3Q 2010 Quarterly Compliance Report) (PPLP004405460) at -470–71.

[110] JX-1833 (Aug. 25, 2016 Quarterly Compliance Report) (PPLPUCC003271544) at -547. *See also* JX-1832 (4Q 2015 Quarterly Compliance Report) (PPLPC063000018836) at -839 ("Provide enhanced training of Commercial management").

[111] JX-2681 (2Q 2015 Quarterly Compliance Report) (PPLP004412152) at -163.

"understand the importance of compliance, and have very good understanding and skills in handling difficult compliance scenarios."[112]

d. The Fourth Element: Lines of Communication and Disclosure

92. The fourth element of an "effective compliance program" is: "Developing effective lines of communication" (the "**Fourth Element**").[113]

93. The quarterly compliance reports informed the Board that Purdue maintained, and continued to enhance, effective "lines of communication" in satisfaction of the Fourth Element because, among other things, (1) the Compliance Department made quarterly compliance reports to the Board, and (2) Purdue established a "Disclosure Program" to facilitate confidential reporting of compliance concerns and continued to develop new "lines of communication" to ensure compliance:[114]

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[112] JX-2661 (4Q 2009 Quarterly Compliance Report) (PPLP004403707) at -716; *id*. at -715 (describing training presentation "Why should compliance matter to you" and compliance "Scenario-based Workshops" given at Purdue's National Sales Meeting).

[113] *See* U.S. DEP'T OF HEALTH AND Human SERVICES, HEALTH CARE COMPLIANCE PROGRAM TIPS, https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf (last visited July 28, 2021).

[114] JX-2687 (Mar. 2018 Quarterly Compliance Report) (PPLP004414931) at -936 ("Created robust communication plan for 2018).

#4 – Disclosure Program

- Purdue maintains a 24 hour toll-free confidential Ethics and Compliance Hotline with "The Network," a third party vendor
  - Callers may remain anonymous
  - Every matter is logged into Axentis by us, no matter how important, and not just Hotline reports
  - Electronic files of every matter are maintained in Axentis
  - Disclosure Log - reviewed at weekly team meetings, at Reportable Events Committee meetings, by Law department
- Purdue policy expressly prohibits retaliation or retribution against any employee for making a good faith report of suspected misconduct or improper behavior
- We regularly publicize our compliance program and our Disclosure Program through training, presentations, e-mails, posters, Purdue's newsletter, and other items

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JX-2664 (3Q 2010 Quarterly Compliance Report) (PPLP004405460) at -476.

94. The Board thus was informed that Purdue had an Ethics and Compliance hotline that provided employees a confidential mechanism to report an ethics or compliance concern or suspected misconduct, or to obtain information and advice regarding the application of Company policies or laws.[115]

95. Purdue's compliance reports regularly informed the Board as to the number and composition of hotline calls received and demonstrated to the Board that management dealt with each of them promptly.[116]

[115] *See also*, *e.g.*, JX-1827 (Aug. 6, 2007 Quarterly Compliance Report) (PPLP004399954) at -959 (reporting that the "Disclosure Program/Hotline" was already in place as of "Day 0" of the CIA).

[116] *See*, *e.g.*, JX-1826 (1Q 2007 Quarterly Compliance Report) (PPLP004399705) at -711–15 (data on hotline calls received: number, subject matter, response time to close inquiry); JX-1829 (1Q 2008 Quarterly Compliance Report) (PPLP004401169) at -181–87 (same; dispositions); JX-2660 (3Q 2009 Quarterly Compliance Report) (PPLP004402982) at -995–99 (same); JX-2663 (2Q 2010 Quarterly Compliance Report) (PPLP004404551) at -563–67 (same); JX-2668 (3Q 2011 Quarterly Compliance Report) (PPLP004406790) at -802–05 (same); JX-1830 (2Q 2012 Quarterly Compliance Report) (PPLPUCC9002892662) at slides 17–19 (same).

96. The Board was also informed that Purdue maintained an "Open Door Policy" for its hotline;[117] that most hotline inquiries were "external inquiries related to medical questions;"[118] that Purdue's hotline received "[l]ower than benchmark percentage anonymous calls;"[119] and that Purdue's compliance team continued to develop new "lines of communication" to ensure compliance.[120]

e. The Fifth Element: Monitoring and Auditing

97. The fifth element of an "effective compliance program" is: "Conducting internal monitoring and auditing" (the "**Fifth Element**").[121]

98. The quarterly compliance reports informed the Board that Purdue actively and effectively monitored the sales force, and conducted a variety of sales force and other audits, to detect and prevent potential violations of law, in satisfaction of the Fifth Element.

99. As the 3Q 2010 Compliance Report summarized:

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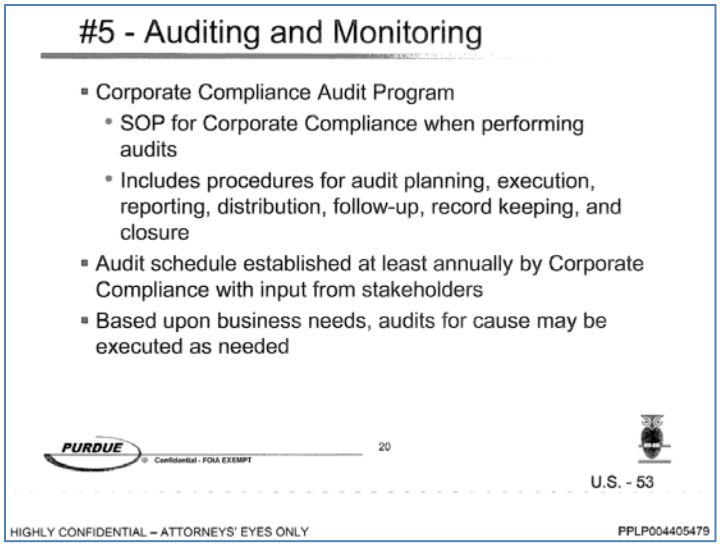
[117] JX-1834 (Mar. 2017 Quarterly Compliance Report) (PPLP004413913) at -917.

[118] JX-2684 (June 2017 Quarterly Compliance Report) (PPLP004414244) at -246.

[119] *Id*. *See also* JX-2687 (March 2018 Quarterly Compliance Report) (PPLP004414931) at -936 ("Hotline volume – remains predominantly external inquiries related to medical questions).

[120] JX-2687 (Mar. 2018 Quarterly Compliance Report) (PPLP004414931) at -936 ("Created robust communication plan for 2018).

[121] *See* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, HEALTH CARE COMPLIANCE PROGRAM TIPS, https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf.



JX-2664 (3Q 2010 Corporate Compliance Quarterly Report) (PPLP004405460) at -479.

100. Purdue management frequently reported to the Board on compliance audits,[122] including audits by third parties.[123]

1. Sales Force Monitoring

101. Throughout the Relevant Period (from mid-2007-2018), the quarterly compliance reports provided the Board with detailed information about Purdue's auditing and monitoring programs.

102. For example, the 2Q 2011 Compliance Report contained a series of slides to

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[122] *See, e.g.*, JX-2656 (3Q 2008 Quarterly Compliance Report) (PPLP004402032) at -058, -081; JX-2666 (1Q 2011 Quarterly Compliance Report) (PPLP004406032) at -047–48; JX-2672 (3Q 2012 Quarterly Compliance Report) (PPLP004408439) at -455; JX-2676 (4Q 2013 Quarterly Compliance Report) (PPLP004410797) at -798, -801, -807–08; JX-2677 (1Q 2014 Quarterly Compliance Report) (PPLP004411166) at -170–73; JX-2678 (2Q 2014 Quarterly Compliance Report) (PPLP004411277) at -282–84; JX-2679 (4Q 2014 Quarterly Compliance Report) (PPLP004411811) at -815; JX-2681 (2Q 2015 Quarterly Compliance Report) (PPLP004412152) at -155; JX-2684 (June 2017 Quarterly Compliance Report) (PPLP004414244) at -246.

[123] JX-2675 (3Q 2013 Quarterly Compliance Report) (PPLP004410506) at -507, -515; JX-2668 (3Q 2011 Quarterly Compliance Report) (PPLP004406790) at -794–97.

answer the questions (1) "How is Purdue's Sales Force Monitored?" and (2) "How Does the Sales Monitoring 'System' Work in Practice?"[124] The slides explained that:

- District Managers monitored each member of the sales force with "Call Note Reviews and 'Call Note Annotations;'" conducted "Ride-Alongs" with each sales rep at least 8 to 12 full days each year; and issued "Field Contact Reports" that provided "detailed documentation and discussion of [each sales] representative's promotion activity" that were "[r]eviewed by Regional Directors and Management."[125]

- Other "Non-D[istrict] M[anager]" monitoring activities included additional "Ride-Alongs" conducted by Corporate Compliance, Field Trainers, the Law Department, Sales Training and others.[126]

- The District Managers' Field Contact Reports were reviewed by Corporate Compliance and each sales representative's compliance performance was "rated against 12 compliance categories," with "any not rated fully compliant result[ing] in detailed review."[127]

- The Compliance Department undertook a "Monthly Call Note Review Process" to "analyze[] all call notes for 30 key words, such as: dosing, formula, benefit, abuse, safer [and] milder."[128] Of over 125,000 call notes generated each month, approximately 25% had "hits," and "[a]ll notes with hits [were] reviewed."[129]

- The Sales force was also monitored for "Abuse, Diversion Detection Reporting," "Speaker Program monitoring," "Hotline matters," "Adverse Event Reporting," "Medical Information Requests," "Product Complaints," "Expense Reporting," "Live Training / Sales meetings," and "Direct contacts to Compliance."[130]

- The Sales Discipline Committee held weekly meetings to track "'sales' investigations matters from inception to conclusion" and determine "individual and

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[124] JX-2667 (2Q 2011 Quarterly Compliance Report) (PPLP004406466) at -482–90.

[125] *Id.* at -483.

[126] *Id*.

[127] *Id*. at -484.

[128] *Id*.

[129] *Id*.

[130] *Id*. at -485.

organizational remediation activities, and discipline."[131]

- Thereafter, the Compliance Council "review[ed] major matters, audits, monitoring activities," and the Sales and Marketing Compliance Committee "address[ed] key compliance risks and issues."[132]

- The outcome for investigations that identified compliance violations by the sales representatives include "Discipline"—from "coaching emails," to "warning letters," to "probation and removal;" "Retraining;" and policy updates to the tools designed to promote compliance.[133]

103. Other quarterly compliance reports informed the Board that Purdue's Compliance Department consistently reviewed, analyzed and appropriately responded to sales representative call notes, anonymous reports submitted to the Purdue's hotline, and expense reports that identified potential violations of company policy or law.[134]

2. Speaker Programs, Payments to HCPs and Other Risks

104. The quarterly compliance reports informed the Board that Purdue carefully monitored and audited business activities involving payments to HCPs to ensure compliance,

[131] *Id*. at -486.

[132] *Id*.

[133] *Id*. at -490.

[134] *See also* JX-2674 (1Q 2013 Quarterly Compliance Report) (PPLP004409694) at -696 (informing Board that Compliance reviewed "10% of approx. 90K call notes generated monthly" and that "[c]ompleting call note reviews this fast has enhanced effectiveness of Sales discipline process"); JX-2675 (3Q 2013 Quarterly Compliance Report) (PPLP004410506) at -510 (providing overview of call note reviewed, issues found, and remediation; "% Reviewed w/Major Findings[:] 0.03%"); JX-2676 (4Q 2013 Quarterly Compliance Report) (PPLP004410797) at -803 ("% Reviewed w/Major Findings[:] 0.19%"); JX-2679 (4Q 2014 Quarterly Compliance Report) (PPLP004411811) at -816 ("Compliance matters are surfaced in many ways, including, call note monitoring, Field Contact Reports, expense and other routine monitoring activities, reports via the Hotline; and from employees and others."); JX-1833 (Aug. 25, 2016 Quarterly Compliance Report) (PPLPUCC003271544) at -546 ("[T]he most common form of discipline continues to be coaching and warning letters"); JX-2684 (June 2017 Quarterly Compliance Report) (PPLP004414244) at -246 ("Call notes to focus on new hires, new product launches").

including:

- **Speaker Programs**. The quarterly compliance reports repeatedly advised the Board that speaker programs were the subject of audits, special attention, and risk reduction efforts.[135] The compliance reports documented the concern that speaker programs were in general a "medium"[136] to "high risk"[137] activity, but the Compliance Department had determined that the risk at Purdue was "low"[138] or "manageable"[139] because there were "appropriate safeguards in place."[140] The Board understood that the safeguards Purdue established to moderate those risks included "[l]ive monitoring" of speeches by "independent monitors" hired to "attend a significant sample of [speaker] programs nation-wide to evaluate and report" to Purdue,[141] plus "monthly monitoring by Corporate Compliance along with Sales Management training on requirements and impact."[142] The Board was apprised of other measures Purdue used to ensure that speaker programs were compliant, such as limits placed on attendees; pre-registration and pre-approval requirements for attendees; "[a]dditional training mandated for all representatives;"

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[135] *See, e.g.*, JX-2678 (2Q 2014 Quarterly Compliance Report) (PPLP004411277) at -284 ("Compliance Audits in Progress — 2Q2014[:] Speaker Programs[:] To assess compliance with speaker program procedures and company guidelines"); JX-2679 (4Q 2014 Quarterly Compliance Report) (PPLP004411811) at -815 ("Completed 13 compliance audits in 2014[.] Areas audited include ... Speaker Programs … Out of these 13 audits, there were a total of 27 findings — 0 Critical"); JX-2680 (1Q 2015 Quarterly Compliance Report) (PPLP004412071) at -073 ("2015 Compliance Priorities ... Speaker Programs"); JX-1833 (Aug. 25, 2016 Quarterly Compliance Report) (PPLPUCC003271544) at -545–46; JX-1834 (Mar. 2017 Quarterly Compliance Report) (PPLP004413913) at -919 ("Enhanced controls and monitoring related to speaker programs"); JX-2684 (June 2017 Compliance Report) (PPLP004414244) at -246 ("Speaker program monitoring continues").

[136] JX-1832 (4Q 2015 Quarterly Compliance Report) (PPLPC063000018836) at -840; JX-2677 (1Q 2014 Quarterly Compliance Report) (PPLP004411166) at -171.

[137] JX-2667 (2Q 2011 Quarterly Compliance Report) (PPLP004406466) at -476; JX-2669 (4Q 2011 Compliance Report) (PPLP004407554) at -563.

[138] JX-2676 (4Q 2013 Quarterly Compliance Report) (PPLP004410797) at -804.

[139] JX-2667 (2Q 2011 Quarterly Compliance Report) (PPLP004406466) at -476.

[140] *Id.*

[141] *Id.* *See also* JX-2669 (4Q 2011 Compliance Report) (PPLP004407554) at -563; JX-2676 (4Q 2013 Quarterly Compliance Report) (PPLP004410797) at -804.

[142] JX-2674 (1Q 2013 Quarterly Compliance Report) (PPLP004409694) at -697 (reporting that, with those measures in place, the risk from non-submission of speaker program monitoring forms was "no longer an issue").

and "[r]efresher training prior to hosting each speaker program."[143] The Compliance Department found "no substantive concerns," and ensured that "minor issues [were] appropriately addressed."[144]

- **OIG Recommendations Concerning Speaker Programs Were Followed.** The Board was also informed that the OIG Monitor, Keshia Thompson, had provided Purdue with "recommendations for good compliance practices in connection with Purdue's ... speaker programs," and that Corporate Compliance was "deeply involved in … establishing fair market value payments for HCPs, training of Purdue District Managers and Representatives, and monitoring arrangements … consistent with OIG' s recommendations."[145]

- **Remuneration to HCPs Was Regulated & in Some Circumstances Barred.** The Board also was advised that Purdue, under the supervision of the General Counsel's office, enforced SOPs and other policies regulating speaker programs and the use of HCPs as speakers, and strictly limiting their remuneration.[146] The policies barred the payment of any fee to an HCP "for the purpose of influencing the HCP to prescribe, order, purchase or recommend any product" and required payments to HCPs be "fair market value" with no tracking for "return on investment."[147]

- **Audits of HCP Remuneration Found No Misconduct or Quid Pro Quos.** The Board was also informed that Purdue's repeated audits did not identify any concerns with remuneration paid to HCPs. For example, the Board was informed that an audit was conducted in 2013 to assess "whether there is a relationship between HCP prescribing of Purdue product, and any financial compensation received from Purdue," and it and found "no correlation."[148] Similarly, the Board

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[143] JX-2676 (4Q 2013 Quarterly Compliance Report) (PPLP004410797) at -805.

[144] JX-2669 (4Q 2011 Quarterly Compliance Report) (PPLP004407554) at -563. *See also* JX-2676 (4Q 2013 Quarterly Compliance Report) (PPLP004410797) at -804 ("risk is low given our remedial and oversight actions").

[145] JX-2059 (4Q 2010 Board Report) (PPLP004366955) at -975; *see also* JX-2666 (1Q 2011 Quarterly Compliance Report) (PPLP004406032) at -033, -035.

[146] JX-1877 (Purdue SOP Num. GC-SOP-0001.04, Retention of HealthCare Professionals as Consultants, Advisors and Speakers) (PPLP003364388); JX-2301 (Purdue Healthcare Law Compliance Policies) (PCA000008931).

[147] JX-1877 (Purdue SOP Num. GC-SOP-0001.04, Retention of HealthCare Professionals as Consultants, Advisors and Speakers) (PPLP003364388) at -389-90, -396. *See also* JX-2301 (Purdue Healthcare Law Compliance Policies) (PCA000008931) at -953 ("It is never appropriate to provide a gift, meal, or entertainment in order to encourage a customer [defined to include an HCP] to prescribe, purchase or order Purdue products.").

[148] JX-2676 (4Q 2013 Quarterly Compliance Report) (PPLP004410797) at -808.

was aware that, when "an audit was conducted to explore whether HCP prescribing might have been influenced by consulting payments or other value received from Purdue," it concluded that "*[t]here was no correlation found between Purdue's financial relationships with HCPs and their prescribing of Purdue products*."[149]

3. Extensive Audits of Other Compliance Areas

105. The Board understood, from the quarterly compliance reports, that Purdue's Compliance Department regularly audited many other types of compliance risks, through and including, *e.g.*, "Call Note Reviews;"[150] "Fee for Service Arrangements;"[151] "Sales Force and Sales Manager Training;"[152] "training course completions;"[153] "Speaker Bureau Program Receipts and Methodology;"[154] "Systems Audit Report[s];"[155] "Topper's Audit;"[156] "Medical

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[149] JX-2681 (2Q 2015 Quarterly Compliance Report) (PPLP004412152) at -155 (italics in original).

[150] JX-2676 (4Q 2013 Quarterly Compliance Report) (PPLP004410797) at -803 ("Call note reviews are a cornerstone of sales compliance, and all notes are reviewed for key words and randomly, within 30 days of each month's-end" — reporting results of review of 25,825 call notes, findings, results and remediation); *see also*, *e.g*., JX-1834 (Mar. 2017 Quarterly Compliance Report) (PPLP004413913) at -917 ("Auditing & Monitoring ● Targeted monitoring activities - call notes (~10%), speaker programs (~10%), ride alongs (~5%)").

[151] JX-2666 (1Q 2011 Quarterly Compliance Report) (PPLP004406032) at -046.

[152] *Id*. at -047 (audit found "all training materials had been approved … and trainers were on topic and consistent with materials").

[153] JX-2672 (3Q 2012 Quarterly Compliance Report) (PPLP004408439) at -455 (reporting monthly auditing and monitoring of training course completions, which "discovered that a new employee was overdue in completing four out of six CIA requirements" and reporting that this was remediated).

[154] *Id.* at -471 (audit to determine compliance to SOP requirements: "Number of Critical Findings: 0").

[155] JX-2675 (3Q 2013 Quarterly Compliance Report) (PPLP004410506) at -515 (Navigant Consulting retained to perform two-part audit of Sunshine Act reporting and found Purdue "'Meets Requirements, Minor Issues Noted,' with most issues addressed already").

[156] JX-2676 (4Q 2013 Quarterly Compliance Report) (PPLP004410797) at -807 (audit assessed "potential that the Annual Topper's Contest might incentivize the Sales Force to inappropriately promote products" and concluding: "No negative findings – no correlation").

Information Requests;"[157] "Material Review[s];"[158] "Field Contact Report Audits;"[159] "Managed Care;"[160] "Aggregate Spend – Commercial;"[161] "field coaching reports;"[162] "Ride Alongs,"[163] "CIA Training;"[164] "Vermont State law sales compliance issues;"[165] "In-Service Sign-in Sheet Audit;"[166] "FCPA / UK Bribery,"[167] and many others.[168]

[157] *Id*. (audit performed to "provide a level of assurance that inquiries received by Medical Services were not solicited and/or [to] confirm whether or not improper promotion may have occurred" and concluding: "No negative findings – no correlation").

[158] JX-2677 (1Q 2014 Quarterly Compliance Report) (PPLP004411166) at -173 (audit to "assess expired status of materials in the APRIMO system" — "No Critical Findings").

[159] *Id.* (assessing "whether District Managers were accurately documenting compliance issues on Field Contact Reports" and concluding: "No Critical Findings; 3 Major Finding (timeliness of expense reporting, poor call notes, accuracy of FCR [field contact report] documentation)").

[160] JX-2678 (2Q 2014 Quarterly Compliance Report) (PPLP004411277) at -283 (audit performed "[t]o provide a level of assurance that Purdue Managed Care Account Executives and Area Managers were performing activities in compliance to the Managed Care SOP," making "No Critical Findings," and reporting "Remediation is underway" for timing of submitting documentation and other lesser matters).

[161] *Id*. (audit to verify "that Sales Representatives were properly documenting expenses related to Health Care Professionals" and making "No Critical Findings").

[162] JX-2684 (June 2017 Quarterly Compliance Report) (PPLP004414244) at -246–47 ("Completed audit of field coaching reports," "Improved field management oversight through increased field ride alongs" and "Enhanced Field Coaching Report format").

[163] *Id*. ("E&C [Ethics & Compliance] Ride alongs continuing"); JX-2687 (Mar. 2018 Compliance Report) (PPLP004414931) at -936 ("Conducted ride alongs for approximately 10% of field sales force").

[164] *See, e.g.*, JX-2666 (1Q 2011 Quarterly Compliance Report) (PPLP004406032) at -046.

[165] *Id.*

[166] *Id*. at -048 (audit found that Sales representatives "conducting HCP in-services meals" had a 92% accuracy rating for data entry and reporting requirements," with improvements from previous year).

[167] *Id*. at -046.

[168] *See* JX-2679 (4Q 2014 Quarterly Compliance Report) (PPLP004411811) at -815 (listing 13 compliance audits in 2014 and reporting "a total of 27 findings — 0 Critical, 18 Major, and 9 Minor," with "All findings … satisfactorily resolved"); JX-1834 (Mar. 2017 Quarterly Compliance

4. Sales Force Compliance: Incentives and Disincentives

106. The Board financially incentivized compliance by making employee bonus payments rise or fall depending on satisfaction of compliance obligations. *See, e.g.*, JX-1910 (1/21/11 Board Compensation Committee deck) (PPLPUCC9003754547) at slide 4,[169] which shows the compliance multiplier of 102.5% used for the company performance portion (75%) of annual bonus determinations in 2010:

2010 Annual Bonus Business Success Scorecard Performance – Proposed Year-End

Category	Components	Factor Weight	Projected Performance Level	Percent Paid	Payout Level
Sales	• Net Branded Sales Goal Attainment versus 2010 Budget of $2,579.6 million	40%	Adjusted Net Sales of $2,472.9 million 95.9% of target	87.9%	35.2%
Operating Efficiency	• Efficiently operating the business to manage expenses within budget • Target Payout at $10 million in qualified savings; Maximum payout at savings of $40 million (excludes R&D and sales volume related expenses)	30%	Qualifying savings of $34.43 million	160.9%	48.3%
Product Diversification	• Advancement of drug development projects through R&D, clinical research, and regulatory milestones •Assessment of the extent to which BD and IP operations contribute to diversification / commercial success	30%	R&D 113.4% LBD 97.5%	105.5%	31.6%
	Total Business Measures	100%			115.1%
	Overarching Objective – Compliance Multiplier				102.5%
	Overall Performance Score				117.9%

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107. Further, if a decision was made to place a prescriber or pharmacist in Region Zero—that is, was placed on PPLP's Do Not Call list because of PPLP concerns about possible

Report) (PPLP004413913) at -919 ("Enhanced monitoring – SOM, ADD, and Healthcare Professional (HCP) Vetting").

[169] *See also* JX-1908 (1/8/10 Scorecard Summary) (PPLPC057000007180); JX-1909 (Feb. 24, 2010 Board Proposal) (PURDUE-COR-00028015) (proposal); JX-1912 (2/16/11 Decision Document) (PPLP004417142) (proposal adopted); JX-1911 (1/24/11 Memo to Board) (PURDUE-COR-00029177); JX-1913 (January 18, 2012 Board Compensation Committee Presentation) (PPLPC042000025057).

diversion—no bonus was earned from prescriptions written by that prescriber or pharmacist.[170]

108. Violations of ADD Program requirements could also result in bonus ineligibility, as well as other disciplinary action, including termination of employment.[171]

109. In 2013, the Board was informed that a Purdue compliance audit found "no correlation" between sales-force incentives—specifically, the Topper's program, which rewarded PPLP's best salespeople in every district and the top 10% nationally[172] —and improper promotion.[173]

f. The Sixth Element: Discipline

110. The sixth element of an "effective compliance program" is: "Enforcing standards through well-publicized disciplinary guidelines" (the "**Sixth Element**").[174]

111. The quarterly reports provided extensive information that the Board relied on to monitor the enforcement of Purdue's compliance standard and related discipline, in satisfaction of the Sixth Element.[175]

112. The quarterly reports informed the Board that the Sales Discipline Committee

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[170] *See, e.g.*, JX-1871 (June 15, 2007 ADD SOP 1.7.1) (PPLP003429997) at -3000; JX-1883 (Sept. 2015 ADD SOP 1.7.1) (PPLP004035073) at -076; JX-1888 (Aug. 2017 ADD SOP 1.7.1) (PPLPC016000316429) at -432.

[171] JX-1883 (Sept. 2015 ADD SOP 1.7.1) (PPLP004035073) at -076; JX-1888 (Aug. 2017 ADD SOP 1.7.1) (PPLPC016000316429) at -432.

[172] JX-2272 (IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 2) (PPLP004433812) at -905–06.

[173] JX-2676 (4Q 2013 Quarterly Compliance Report) (PPLP004410797) at -807.

[174] *See* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, HEALTH CARE COMPLIANCE PROGRAM TIPS, https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf (last visited July 28, 2021).

[175] *See, e.g.*, JX-2664 (3Q 2010 Quarterly Compliance Report) (PPLP004405460) at -486.

held regular meetings to "[r]eview open issues, determine discipline, [and] maintain records of decisions," and the Law Department maintained a "[c]onfidential discipline database."[176]

113. Quarterly reports to the Board reflected that the vast majority of the compliance issues identified by the Compliance Department were not significant[177] and that Purdue addressed all violations through discipline—ranging from warning letters, training and coaching to probation and termination.[178]

g. The Seventh Element: Investigations and Remediation

114. The seventh element of an "effective compliance program" is: "Responding

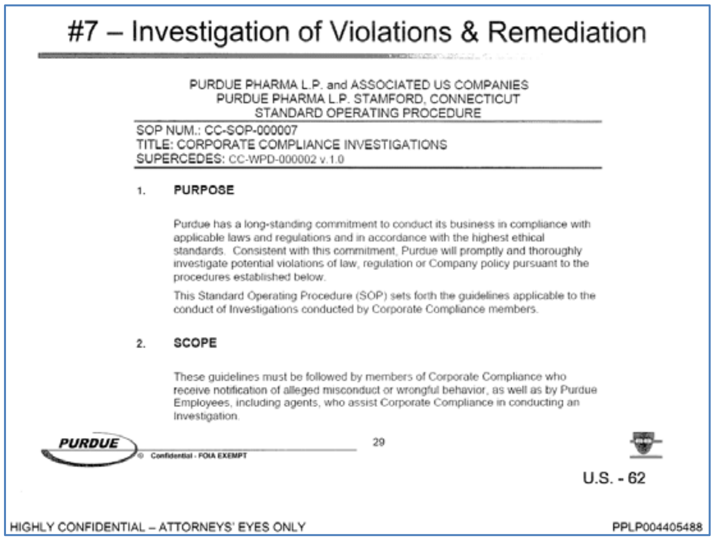
[176] *See id.* at -487.

[177] *See, e.g.*, JX-2675 (3Q 2013 Quarterly Compliance Report) (PPLP004410506) at -507 ("no significant violations or gaps"); JX-2676 (4Q 2013 Quarterly Compliance Report) (PPLP004410797) at -809 ("No significant compliance risks"); JX-2677 (1Q 2014 Quarterly Compliance Report) (PPLP004411166) at -167 ("No significant compliance issues"); JX-2678 (2Q 2014 Quarterly Compliance Report) (PPLP004411277) at -278 ("No significant compliance issues"); JX-2679 (4Q 2014 Quarterly Compliance Report) (PPLP004411811) at -812 ("no significant compliance issues"); JX-2680 (1Q 2015 Quarterly Compliance Report) (PPLP004412071) at -072 ("no significant compliance issues"); JX-2681 (2Q 2015 Quarterly Compliance Report) (PPLP004412152) at -153 ("no significant compliance issues"); JX-2682 (3Q 2015 Quarterly Compliance Report) (PPLP004412546) at -547 ("no significant compliance issues"); JX-1832 (4Q 2015 Quarterly Compliance Report) (PPLPC063000018836) at -837 ("no significant compliance issues"); JX-1833 (Aug. 25, 2016 Quarterly Compliance Report) (PPLPUCC003271544) at -545 ("no *significant* compliance matters") (italics in original); JX-2684 (June 2017 Quarterly Compliance Report) (PPLP004414244) at -425 ("no significant compliance issues"); JX-2687 (Mar. 2018 Quarterly Compliance Report) (PPLP004414931) at -932 ("No significant compliance issues").

[178] *See, e.g.*, JX-1829 (1Q 2008 Quarterly Compliance Report) (PPLP004401169) at -184; JX-2655 (2Q 2008 Quarterly Compliance Report) (PPLP004401342) at -348–49; JX-2657 (4Q 2008 Quarterly Compliance Report) (PPLP004402205) at -212; JX-2058 (3Q 2010 Board Report) (PPLP004366991) at -7004; JX-2667 (2Q 2011 Quarterly Compliance Report) (PPLP004406466) at -490; JX-2679 (4Q 2014 Quarterly Compliance Report) (PPLP004411811) at -816; JX-2684 (June 2017 Quarterly Compliance Report) (PPLP004414244) at -246.

promptly to detected offenses and undertaking corrective action" (the "**Seventh Element**").[179]

115. The Board used the quarterly compliance reports to monitor the investigation and remediation activities, which satisfied the Seventh Element. *See, e.g.*, JX-2664 (3Q 2010 Quarterly Compliance Report) (PPLP004405460) at -488:



#7 – Investigation of Violations & Remediation

PURDUE PHARMA L.P. and ASSOCIATED US COMPANIES
PURDUE PHARMA L.P. STAMFORD, CONNECTICUT
STANDARD OPERATING PROCEDURE

SOP NUM.: CC-SOP-000007
TITLE: CORPORATE COMPLIANCE INVESTIGATIONS
SUPERCEDES: CC-WPD-000002 v.1.0

1. **PURPOSE**

Purdue has a long-standing commitment to conduct its business in compliance with applicable laws and regulations and in accordance with the highest ethical standards. Consistent with this commitment, Purdue will promptly and thoroughly investigate potential violations of law, regulation or Company policy pursuant to the procedures established below.

This Standard Operating Procedure (SOP) sets forth the guidelines applicable to the conduct of Investigations conducted by Corporate Compliance members.

2. **SCOPE**

These guidelines must be followed by members of Corporate Compliance who receive notification of alleged misconduct or wrongful behavior, as well as by Purdue Employees, including agents, who assist Corporate Compliance in conducting an Investigation.

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116. Through the quarterly reports, the Board understood that Purdue was implementing the Compliance Charter through policies and procedures that required the Compliance Department to "promptly and thoroughly investigate potential violations of law, regulation or Company policy."[180]

117. The compliance reports gave the Board a detailed overview of sample investigations showing how Purdue's compliance program worked in practice,[181] as well as

[179] *See* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, HEALTH CARE COMPLIANCE PROGRAM TIPS, https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf (last visited July 28, 2021).

[180] JX-2664 (3Q 2010 Quarterly Compliance Report) (PPLP004405460) at -488.

[181] JX-2667 (2Q 2011 Quarterly Compliance Report) (PPLP004406466) at 489–90 (telling Board: "Law and Compliance reviewed all email"; compliance "[c]onducted investigations with representatives who had more significant violations"; "Major discipline for one representative").

status updates and data confirming that Purdue regularly performed investigations and remediation.[182]

118. The quarterly compliance reports reflect that the Board was interested in the status of the Compliance Department's investigations and affirmatively requested that the Compliance Department "continue past practice of providing the Board with quarterly data" about those efforts.[183]

B. The Board Was Advised That All Aspects of Purdue's Compliance Program Were Properly Functioning and Exceeded Industry Standards

119. The Board understood—based on the many years of regular and substantial reporting from management—that all aspects of Purdue's compliance program were fully and properly functioning.

120. The management reports enumerated Purdue's compliance efforts in detail, identifying issues that had arisen and steps taken by the Compliance Department to resolve them.

121. Year in and year out, the reports concluded with management's reasoned determination that Purdue had satisfied all of its compliance obligations during the relevant period. For example:

- **2007**: "Purdue is in full compliance with AG Agreement" ●"Purdue is in full

[182] JX-2655 (2Q 2008 Quarterly Compliance Report) (PPLP004401342) at -356–57 (updating Board on ongoing investigations and reporting investigation of "106 matters in 2Q08," of which "10 had compliance implications"); JX-2679 (4Q 2014 Quarterly Compliance Report) (PPLP004411811) at -817 (describing "Most Important Investigation of 2014"); JX-2682 (3Q 2015 Quarterly Compliance Report) (PPLP004412546) at -551 ("Matters by Quarter"); JX-1834 (Mar. 2017 Quarterly Compliance Report) (PPLP004413913) at -917 ("More than 250 inquiries and matters addressed in 2016"); JX-2687 (Mar. 2018 Quarterly Compliance Report) (PPLP004414931) at -940 (detail on "Investigations and Inquiries: YTD 2018").

[183] JX-2682 (3Q 2015 Quarterly Compliance Report) (PPLP004412546) at -550.

compliance with CIA" ● "Full compliance with State Law Requirements"[184]

- **2008**: "First Annual Report to OIG submitted ... certifies to all CIA requirements" ● "Purdue is also in full compliance with its AG Agreements" ● "State Law Reporting Update ... No compliance issues identified"[185]

- **2009**: "Review of call notes and other monitoring has uncovered[:] No Improper Promotion ● No Inappropriate discussion of abuse, diversion, tolerance, withdrawal ● No violations of Law" ● "State Law Reporting Update ... No compliance issues identified"[186]

- **2010**: "Year three of Purdue's five year CIA closes as of July 30, with all requirements met...."[187]

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184 JX-1827 (Aug. 6, 2007 Compliance Report) (PPLP004399954) at -955*; see also* JX-2047 (3Q 2007 Board Report) (PPLPC012000157402) at -461 ("We investigated a total of 39 ... matters during the third quarter of 2007. None of these matters were of significant concern"); JX-2048 (4Q 2007 Board Report) (PPLP004367604) at -629 ("We investigated a total of 83 ... matters during the fourth quarter of 2007. None of these matters were of significant concern").

185 JX-2656 (3Q 2008 Quarterly Compliance Report) (PPLP004402032) at -036, -044. *See also, e.g.*, JX-1828 (Feb. 8, 2008 Quarterly Compliance Report) (PPLPC019000195607) at slide 3 ("Purdue in compliance with AG Agreements"); JX-1829 (1Q 2008 Quarterly Compliance Report) (PPLP004401169) at -171 ("Purdue in compliance with AG Agreements"); JX-2049 (1Q 2008 Board Report) (PPLP004367134) at -157 ("We investigated a total of 83 ... matters during the first quarter of 2008. None of these matters were of significant concern"); JX-2689 (2Q 2008 Board Report) (PPLP004367297) at -324 ("We investigated a total of 93 ... matters during the second quarter of 2008. None of these matters were of significant concern"); JX-2656 (3Q 2008 Quarterly Compliance Report) (PPLP004402032) at -036 ("Purdue is ... in full compliance with its AG Agreements"); JX-2657 (4Q 2008 Quarterly Compliance Report) (PPLP004402205) at -220 ("No compliance issues identified").

186 JX-2658 (1Q 2009 Quarterly Compliance Report) (PPLP004402651) at -654, -665. *See also* JX-2659 (2Q 2009 Quarterly Compliance Report) (PPLPC012000236639) at slide 3 ("All requirements were fully met for CIA year 2, ended 7/30/09"); JX-2660 (3Q 2009 Quarterly Compliance Report) (PPLP004402982) at -984 ("all requirements fully met for CIA year 2, ended 7/30/09"); *id.* at -986 ("Purdue is ... in full compliance with its AG Agreements"); JX-2661 (4Q 2009 Quarterly Compliance Report) (PPLP004403707) at -718 ("No significant matters outstanding").

187 JX-2057 (2Q 2010 Board Report) (PPLP004367018) at -034. *See also* JX-2662 (1Q 2010 Quarterly Compliance Report) (PPLP004404102) at -104 (advising the Board that the OIG of HHS confirmed in writing that "it appears that Purdue was in compliance with the terms of the Corporate Integrity Agreement ... during the second annual reporting period"); JX-2665 (4Q 2010 Quarterly

- **<u>2011</u>**: "All requirements under the CIA have been met in Reporting Period 4, including all critical field-based CIA requirements" ● "Marketing & Sales ... No compliance shortcomings to report"[188]

- **<u>2012</u>**: "[T]he Company continued to maintain a state of effective compliance"[189]

- **<u>2013</u>**: "There are no significant violations or gaps to report"[190]

Compliance Report) (PPLP004405709) at -711 ("CIA Year #3 closed 7/30/10, with 100% completion of all requirements").

[188] JX-2705 (2Q 2011 Board Report) (PPLP004366913) at -915, -920, -940. *See also* JX-2666 (1Q 2011 Quarterly Compliance Report) (PPLP004406032) at -034, -050 (reporting on and forwarding letter from OIG of HHS confirming that "it appears that Purdue was in compliance with the terms of the Corporate Integrity Agreement" for year 3 of the CIA); JX-2667 (2Q 2011 Quarterly Compliance Report) (PPLP004406466) at -468 ("All requirements under the CIA have been met in Reporting Period 4, including all critical field-based CIA requirements"); JX-2060 (3Q 2011 Board Report) (PPLP004366871) at -896 ("All requirements under Purdue's CIA have been met in Reporting Year 4").

[189] JX-2673 (4Q 2012 Quarterly Compliance Report) (PPLP004409357) at -363. *See also* JX-2670 (1Q 2012 Quarterly Compliance Report) (PPLP004407950) at -950 ("Corporate Integrity Agreement — no significant issues in 1Q12"); JX-2672 (3Q 2012 Quarterly Compliance Report) (PPLP004408439) at -449 ("Through the Third Quarter, the Company continues to maintain a state of effective compliance. . . . There have been no significant compliance matters to report for the third quarter"); JX-2673 (4Q 2012 Quarterly Compliance Report) (PPLP004409357) at -363 ("Throughout 4Q12, the Company continued to maintain a state of effective compliance").

[190] JX-2675 (3Q 2013 Quarterly Compliance Report) (PPLP004410506) at -507 (also reporting that: "The Company continues to have good systems and processes in place committed to the prevention and detection of violations, with continuous attention to improvement"). *See also* JX-2693 (1Q 2013 Board Report) (PPLP004367540) at -591 ("Throughout the First Quarter, the Company continues to maintain a state of effective compliance. . . . [T]here have been no significant compliance matters to report."); JX-2674 (1Q 2013 Quarterly Compliance Report) (PPLP004409694) at -695 (quoting OIG letter confirming that "it appears that Purdue was in compliance with the terms of the Corporate Integrity Agreement ... during the fifth annual reporting period"); JX-2066 (2Q 2013 Board Report) (PPLPC012000433388) at -436 ("Throughout the Second Quarter, the Company continues to maintain a state of effective compliance. . . . [T]here have been no significant compliance matters to report"); JX-2067 (3Q 2013 Board Report) (PPLPC002000186911) at -956 ("Throughout 3Q13, the Company continues to maintain a state of effective compliance. . . . [T]here have been no significant compliance matters to report"); JX-2676 (4Q 2013 Quarterly Compliance Report) (PPLP004410797) at -798 ("There are no significant compliance violations to report"); JX-2068 (4Q 2013 Board Report) (PPLPC002000181035) at -073 ("Throughout the 4th Quarter, the Company continues to maintain a state of effective compliance. . . . [T]here have been no significant compliance exposures to

- **2014**: "There have been no significant compliance issues in ... Full Year 2014"[191]
- **2015**: "There have been no significant compliance issues"[192]
- **2016**: "In 2016, there were no significant compliance issues"[193]
- **2017**: "No significant compliance issues to report"[194]

122. Board minutes also reflect, in summary form, that, throughout the duration of the CIA, the VP of Compliance repeatedly reported to the Board that "no significant compliance issues currently exist" and that Purdue "is in full compliance with its compliance requirements including but not limited to the Corporate Integrity Agreement."[195]

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report. The Company continues to have a compliant culture, and good systems and processes in place to prevent violations of law, regulations, and other standards.").

[191] JX-2679 (4Q 2014 Quarterly Compliance Report) (PPLP004411811) at -812. *See also* JX-2677 (1Q 2014 Quarterly Compliance Report) (PPLP004411166) at -167 ("No significant compliance issues to date in 2014"); JX-2678 (2Q 2014 Quarterly Compliance Report) (PPLP004411277) at -278 ("No significant compliance issues in the 2nd quarter, or to date in 2014").

[192] JX-2680 (1Q 2015 Quarterly Compliance Report) (PPLP004412071) at -072. *See also* JX-2681 (2Q 2015 Quarterly Compliance Report) (PPLP004412152) at -153 ("There have been no significant compliance issues in the 2nd quarter, 2015"); JX-2682 (3Q 2015 Quarterly Compliance Report) (PPLP004412546) at -547 ("There have been no significant compliance issues in the 3rd quarter, 2015"); JX-1832 (4Q 2015 Quarterly Compliance Report) (PPLPC063000018836) at -837 ("There have been no significant compliance issues in the 4th quarter, 2015").

[193] JX-1834 (Mar. 2017 Quarterly Compliance Report) (PPLP004413913) at -917. *See also* JX-1833 (Aug. 25, 2016 Quarterly Compliance Report) (PPLPUCC003271544) at -545 ("Throughout the first half of 2016, the Company maintained compliance with applicable laws and regulations ... [T]here have been no significant compliance matters to report").

[194] JX-2687 (Mar. 2018 Quarterly Compliance Report) (PPLP004414931) at -932. *See also* JX-2684 (June 2017 Quarterly Compliance Report) (PPLP004414244) at -245 ("There are no significant compliance issues to report").

[195] JX-2013 (5/11/07 PPI Minutes) (PPLP004415283) ("no significant compliance issues currently exist"); JX-2014 (8/6/07 PPI Minutes) (PPLP004415309) ("the Partnership acknowledges that it was reported that <u>it is in full compliance with its compliance requirements</u> including but not limited to the Corporate Integrity Agreement"). *See also* JX-2016 (2/14/08 PPI Minutes) (PPLP004415351) ("the <u>Partnership is in full compliance</u> with its compliance requirements"); JX-2020 (2/5/09 PPI Minutes) (PPLP004415482) ("the <u>Partnership is in full compliance</u> with its

123. The Board was informed that Purdue's compliance program met or exceeded industry standards. For example:

a. In 2009, when the Board asked management to "consider augmenting Purdue's compliance program to implement new features contained in the most recent CIAs," the VP of Corporate Compliance told the Board that Purdue was already "ahead of the curve" and provided a detailed chart showing "Recent CIA Compliance Requirements" applicable to other companies and how favorably Purdue stacked up.[196]

b. Similarly, in 2012, the Compliance Department reported to the Board that Purdue's compliance program was "State of the Art," and would remain so even after the CIA ended at the end of that month.[197] The report walked the Board through new elements that the most recent CIAs adopted and informed the Board that it was the practice of the Compliance Department to "continually review and selectively implement practices" that it concluded would be the "[f]uture … [f]ocus" of compliance efforts.[198]

124. The Board also understood that its oversight of Purdue's compliance program

compliance requirements"); JX-2022 (5/8/09 PPI Minutes) (PPLP004415535) ("<u>no significant compliance issues</u> currently exist"); JX-2023 (10/19/09 PPI Minutes) (PPLP004415611) ("<u>no significant compliance issues</u> currently exist"); JX-2027 (11/18/10–11/19/10 PPI Minutes) (PPLP004415771) ("the <u>Partnership is in full compliance</u> with its compliance requirements"); JX-2029 (2/3/11 PPI Minutes) (PPLP004415797) ("the <u>Partnership is in full compliance</u> with its compliance requirements"); JX-2031 (7/21/11 PPI Minutes) (PPLP004415826) ("the <u>Partnership is in full compliance</u> with its compliance requirements"); JX-2033 (11/2/11 PPI Minutes) (PPLP004415835) ("the <u>Partnership is in full compliance</u> with its compliance requirements"); JX-2034 (1/19/12 PPI Minutes) (PPLP004415845) ("the <u>Partnership is in full compliance</u> with its compliance requirements"); JX-2037 (7/19/12 PPI Minutes) (PPLP004415869) ("the <u>Partnership is in full compliance</u> with its compliance requirements").

[196] JX-2661 (4Q 2009 Quarterly Compliance Report) (PPLP004403707) at -722–23.

[197] JX-1830 (2Q 2012 Quarterly Compliance Report) (PPLPUCC9002892662) at slide 11.

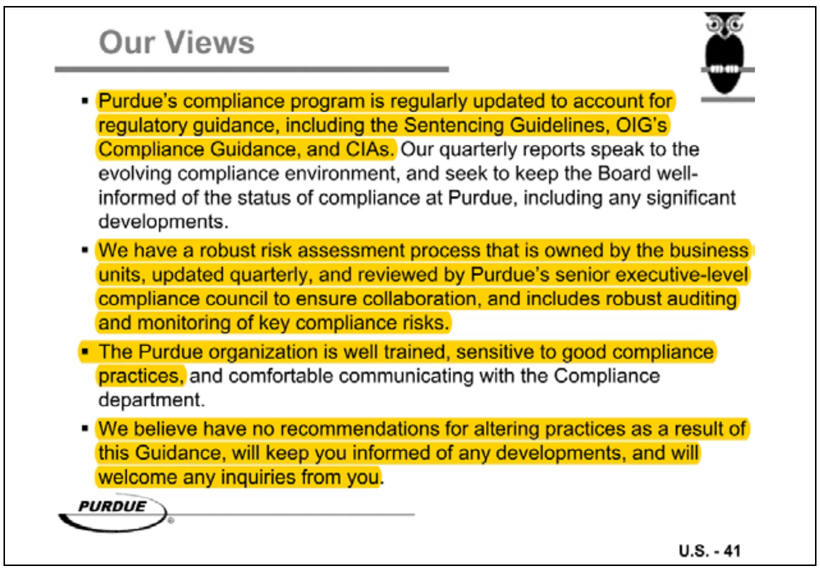
[198] *Id.* at slides 12, 14–15. *See also* JX-2673 (4Q 2012 Quarterly Compliance Report) (PPLP004409357) at -361 ("New (2012) CIA Requirements ... Purdue's Compliance department considers and adopts new OIG requirements to our compliance program, where applicable"); JX-2676 (4Q 2013 Quarterly Compliance Report) (PPLP004410797) at -800 ("We review each new CIA (as well as other external sources), and consider whether to adopt new requirements into Purdue's compliance program").

satisfied the OIG's evolving standards for Board oversight.[199]

a. In 2015, the Board was informed of the OIG's newly published *Practical Guidance for Health Care Governing Boards on Compliance Oversight*, a complete copy of which was provided to the Board and was the subject of a detailed presentation by the Compliance Department.[200]

b. The Compliance Department's presentation to the Board set out the OIG's "Expectations for Board Oversight" and how the established practices of the PPI Board satisfied those expectations.[201]

c. The Board was advised that its oversight of the compliance program, and the compliance program itself, satisfied the OIG expectations (JX-2681 (2Q 2015 Quarterly Compliance Report) (PPLP004412152) at -163)):



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[199] *See* JX-2664 (3Q 2010 Quarterly Compliance Report) (PPLP004405460) at -465 ("Purdue's compliance program has also been implemented pursuant to the OIG Compliance Program Guidance for Pharmaceutical Manufacturers").

[200] *See* JX-2681 (2Q 2015 Quarterly Compliance Report) (PPLP004412152) (attaching *Practical Guidance of Health Care Governing Boards on Compliance Oversight*). *See also* https://oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf.

[201] JX-2681 (2Q 2015 Quarterly Compliance Report) (PPLP004412152) at -157–58.

1. The OIG and the IRO Monitored and Confirmed Purdue's Compliance Efforts From July 31, 2007 Through July 30, 2012

125. Management's reports to the Board confirming that Purdue's compliance program was functioning properly were independently verified by independent monitors from July 31, 2007 to July 30, 2012, when Purdue operated under the CIA.

126. The CIA imposed strict compliance and reporting requirements and placed Purdue under the monitorship of the OIG and the IRO.[202]

127. For each one-year Reporting Period from July 31, 2007 through July 30, 2012, the Board was informed that the OIG had confirmed in writing Purdue's compliance with the CIA.[203] The Board was also advised that the OIG Monitor, Keshia Thompson, orally expressed her approval of the Purdue's compliance efforts at various points during the 5-year monitorship. For example, in 2010, OIG Monitor Thompson told Purdue that its employees "consistently

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[202] *See* CIA at ¶¶III.C.4., III.D.1.

[203] *See* JX-2659 (2Q 2009 Quarterly Compliance Report) (PPLPC012000236639) at slide 6 ("By May 6th letter, OIG confirmed Purdue's compliance with the requirements of our CIA during the first year, based on their review of our Annual Report and other materials."); JX-2056 (1Q 2010 Board Report) (PPLP004317547) at -559 ("By letter dated April 1st, Purdue's OIG Monitor confirmed that ... Purdue was in compliance with the terms of its Corporate Integrity Agreement during the second reporting period"); JX-2692 (1Q 2011 Board Report) (PPLPC012000322426) at -448 ("We have received the Office of Inspector General's (OIG) January 28th letter confirming satisfactory completion of their review of Purdue's Third Annual Report: 'it appears that Purdue was in compliance with the terms of the Corporate Integrity Agreement'"); JX-1839 (3/8/12 OIG Letter to Purdue) (PPLP004428603) at -603 (Based on our review of this additional information and the information provided in Purdue's Fourth Annual Report, it appears that Purdue was in compliance with the terms of the Corporate Integrity Agreement (CIA) … during the fourth annual reporting period."); JX-1840 (1/24/13 OIG Letter to Purdue) (PPLP004427723) at -723 "Based on our review of all this information, it appears that Purdue was in compliance with the terms of the Corporate Integrity Agreement (CIA) during the fifth annual reporting period."); JX-2674 (1Q 2013 Quarterly Compliance Report) (PPLP004409694) at-695 ("From Letter dated January 24th, Office of Inspector General, HHS: ...'[I]t appears that Purdue was in compliance with the terms of the Corporate Integrity Agreement (CIA) … during the fifth annual reporting period.... [T]he Purdue CIA has now concluded.'").

demonstrated compliance knowledge and awareness,"[204] and in 2009, OIG Monitor Thompson "was impressed to hear of the seriousness Purdue's sales force and management attached to" compliance matters.[205]

128. Every year the CIA was in effect, Huron Consulting Services LLC ("**Huron**") served as IRO under the CIA to "verify [Purdue's] 'systems, policies, processes, and procedures,'" and to audit Purdue's "data relating to promotion and dissemination of information of [*sic*] Purdue Products."[206]

129. Huron documented its findings in eight comprehensive reports.[207]

130. Every year, the IRO examined selected Purdue areas of activity, including those relating to sales force communications with HCPs, conducted interviews, and assessed whether Purdue properly handled potential violations.[208]

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[204] JX-2664 (3Q 2010 Quarterly Compliance Report) (PPLP004405460) at -498.

[205] JX-2660 (3Q 2009 Quarterly Compliance Report) (PPLP004402982) at -985.

[206] JX-1827 (Aug. 6, 2007 Quarterly Compliance Report) (PPLP004399954) at -965.

[207] *See* JX-2260 (IRO's Report on Promotional and Product Services Transactions Engagement, Reporting Period 1) (PPLPC057000008159); JX-2272 (IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 2) (PPLP004433812); JX-2276 (IRO's Report on Promotional and Product Services Transactions Engagement, Reporting Period 2) (PPLP004433931); JX-2291 (IRO's Report on Additional Promotional and Product Services Systems Assessment: Funding of Charitable Grants and Sponsorships, Reporting Period 3) (PPLP004434741); JX-2292 (IRO's Report on Promotional and Product Services Transactions Engagement, Reporting Period 3) (PPLP004434457); JX-2315 (IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 4) (PPLPC021000573227); JX-2314 (IRO's Promotional and Product Services Transactions Engagement, Reporting Period 4) (PPLP004432560); JX-2338 (IRO's Report on Promotional and Product Services Transactions Engagement, Reporting Period 5) (PPLP004434983).

[208] *See* JX-2260 (IRO's Report on Promotional and Product Services Transactions Engagement, Reporting Period 1) (PPLPC057000008159) (describing Workplan procedures for inquiry-testing); JX-2276 (IRO's Report on Promotional and Product Services Transactions Engagement, Reporting Period 2) (PPLP004433931) (same); JX-2292 (IRO's Report on Promotional and Product Services Transactions Engagement, Reporting Period 3) (PPLP004434457) (same); JX-

131. In 2009 and 2011, the IRO produced additional reports detailing what each relevant policy or procedure at Purdue entailed, how Purdue trained its employees, how it monitored employees for compliance with Purdue policies, and how it disciplined violators.[209]

132. The IRO also prepared an additional report in 2010 concerning Purdue's revision to its Healthcare Grant Review Committee SOP.

133. To the extent the IRO made any negative findings, the Board understood they were minor, and Purdue appropriately responded to the IRO's recommendations.[210]

2. The Board Understood That Purdue Enhanced Its Compliance Efforts After The CIA Ended

134. On July 19, 2012, shortly before the 5-year term of the CIA ended, the Compliance Department presented a detailed report to the Board on Purdue's "Post-CIA Compliance Program," explaining in detail that the program in force under the CIA would continue essentially intact with some refinements (*e.g.*, elimination of OIG and IRO reporting

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2314 (IRO's Promotional and Product Services Transactions Engagement, Reporting Period 4) (PPLP004432560) (same); JX-2338 (IRO's Report on Promotional and Product Services Transactions Engagement, Reporting Period 5) (PPLP004434983) (same).

[209] *See* JX-2272 (IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 2) (PPLP004433812) at -815 (outline of assessment of "Promotional and Product Services Systems"); JX-2291 (IRO's Report on Additional Promotional and Product Services Systems Assessment: Funding of Charitable Grants and Sponsorships, Reporting Period 3) (PPLP004434741) at -743–44 (outline of assessment of "Promotional and Product Services Systems" after Purdue had "revised its Healthcare Grant Review Committee … SOP"); JX-2315 (IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 4) (PPLPC021000573227) at -232 (outline of procedures for assessment of "Promotional and Product Services Engagement").

[210] *See*, *e.g.*, JX-2656 (3Q 2008 Quarterly Compliance Report) (PPLP004402032) at -038 ("non-significant findings"; "All recommendations to be accomplished no later than 12/08"); JX-2060 (3Q 2011 Board Report) (PPLP004366871) at -896 (the IRO report "contains a limited number of minor observations and recommendations, to which the company responded"); JX-2064 (3Q 2012 Board report) (PPLP004366816) at -860 ("All [IRO] findings and observations are minor").

requirements and incidental obligations), under the direction of the Compliance Department and the supervision of the Compliance Council.[211]

135. The 2Q 2012 Compliance Report explained:

- "We will <u>continue to address compliance risks company-wide</u>."
- "We will <u>continue to do nearly all CIA-required compliance activities</u>."
- "We will drop a small percentage of total workload that was OIG-centric (e.g., reporting to OIG), but <u>expand other valuable activities</u>."[212]

136. The 2Q 2012 Compliance Report informed the Board of the long list of compliance "Activities To be Continued," including quarterly reports to the Board; investigation of hotline matters and compliance issues raised in Sales Discipline; and continued escalation of "significant matters" that had been "Reportable Events" under the CIA to "Law and Compliance" and to the Corporate Compliance Council for review and redress.[213]

137. The 2Q 2012 Compliance Report informed the Board that Purdue would "continually review and selectively implement practices that" the Compliance Department believed would "add compliance value" for the Company.[214]

138. **Outside Counsel's Compliance Role.** The 2Q 2012 Compliance Report informed the Board that, in anticipation of the IRO monitorship concluding, Purdue had retained

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[211] *See* JX-1830 (2Q 2012 Quarterly Compliance Report) (PPLPUCC9002892662) at slide 3.

[212] *Id*. (emphasis added).

[213] *Id*. at slide 5. *See also id.* at slides 6–8. "Reportable Events" encompass "anything that involves a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program and/or any FDA requirements relating to the labeling or promotion of products...." CIA at ¶III(H).

[214] JX-1830 (2Q 2012 Quarterly Compliance Report) (PPLPUCC9002892662) at slide 12.

outside counsel—a health-law expert at a major law firm.[215]

139. The Board was informed that outside counsel—which had provided advice to PPLP on compliance matters as early as 2010[216]—would "[p]rovide ongoing reviews of Compliance Program effectiveness and improvements," "[m]eet with [the] Corporate Compliance Council and other select Committees as an outside resource," and "[c]onsult with [the] Compliance Department."[217] In 2016, Purdue updated its retention of outside counsel to continue to provide "proactive legal and compliance reviews."[218]

140. **Outside Counsel Compliance Review.** In 2016, the Board was informed that, in the fourth quarter of 2015, outside counsel had conducted a compliance review of PPLP's field promotional activities and that outside counsel gave a positive review of the Commercial Compliance program.[219] Management advised the Board that outside counsel had concluded that compliance controls were consistent with industry practice and requirement established in recent Corporate Integrity Agreements between the HHS OIG and pharmaceutical manufacturers.[220]

141. The Board understood that outside counsel suggested some program enhancements, and that they were implemented.[221]

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[215] *See id.* at slide 7.

[216] *See* Declaration of Patrick Fitzgerald, Esq. at ¶4, *In re Purdue Pharma L.P.*, Case No. 19-23649-rdd (Bankr. S.D.N.Y. Nov. 5, 2019), ECF No. 438-2.

[217] JX-1830 (2Q 2012 Quarterly Compliance Report) (PPLPUCC9002892662) at slide 7.

[218] Declaration of Patrick Fitzgerald, Esq. at p. 21 (Ex. 1-B), *In re Purdue Pharma L.P.*, Case No. 19-23649-rdd (Bankr. S.D.N.Y. Nov. 5, 2019), ECF No. 438-2.

[219] JX-1832 (4Q 2015 Quarterly Compliance Report) (PPLPC063000018836) at slide -837.

[220] JX-2683 (Quarterly Ethics & Compliance & Report to Board of Directors for 3Q2016 (Dec. 1, 2016) (PPLPUCC9002790025) at p. 3.

[221] JX-1834 (March 2017 Quarterly Compliance Report) (PPLP004413913) at –920 ("Complete deployment" of outside counsel's "enhancements"). *See also* JX-1833 (Aug. 25, 2016 Quarterly

IV. THE FORMER DIRECTORS RESPONSIBLY MONITORED PURDUE'S ANTI-DIVERSION PROGRAMS

142. PPLP did not control the use and dissemination of its opioid medications after it sold and delivered its products to distributors, but PPLP implemented and maintained anti-diversion programs—including the ADD Program,[222] the Suspicious Order Monitoring ("**SOM**") Program,[223] and the Order Monitoring System ("**OMS**") Program[224]—which management consistently reported to the Board were being properly executed.

143. The Board did not have a day-to-day role in implementing Purdue's anti-diversion activities but responsibly monitored management's anti-diversion efforts, which were catalogued in detailed compliance and other reports consistently confirming to the Board that:

- Purdue was actively implementing and monitoring the ADD Program.[225]

Compliance Report) (PPLPUCC003271544) at –546–475 ("During Q4 2015, a compliance review was conducted by outside counsel … which focused on field promotional activities and compliance controls in place with respect to those activities. . . . [The] review identified a limited number of discretionary opportunities for enhancement of the compliance program, one of which was regular email monitoring of the field . . . . the Ethics & Compliance team has developed an email monitoring methodology and selected a system to conduct a monitoring pilot by year end. The pilot is scheduled to begin in the third quarter. . . .").

222 Originally, the ADD Program was entitled "Indicators of Possible Diversion." *See* JX-1863 (10/15/02 ADD SOP) (PDD1503450011); JX-1864 (11/1/02 ADD SOP 1.7.1) (PPLP003430434); JX-1867 (10/6/03 ADD SOP 1.7.1) (PDD1503493410). Purdue rebranded it as the ADD Program in 2007, in connection with entry into the Corporate Integrity Agreement. *See* JX-1871 (6/15/07 ADD SOP 1.7.1) (PPLP003429997); JX-1883 (Sept. 2015 ADD SOP 1.7.1) (PPLP004035073); *see also, e.g.*, JX-1888 (Aug. 2017 ADD SOP 1.7.1) (PPLPC016000316429). All iterations of the program are referred to as the "**ADD Program**" in this filing.

223 *See* JX-1865 (3/12/03 SOM SOP) (PPLPC035000019501).

224 *See* JX-2288 (07/21/10 Presentation to Corporate Compliance Council entitled "The Order Monitoring System") (PPLPC041000011499).

225 *See, e.g.*, JX-1827 (Aug. 6, 2007 Quarterly Compliance Report) (PPLP004399954) at -955–58, -968, -970) ("Purdue is in full compliance with AG Agreement" (Purdue's shorthand for the 27 Consent Judgments it entered in 2007), including establishment of ADD Program and timely certification of same; management handling 2 reported abuse/diversion matters pursuant to SOP

- All employees were trained on the ADD Program.[226]

1.7.1 (ADD Program)/resolving 4 compliance inquiries regarding abuse/diversion/theft); JX-1828 (Feb. 8, 2008 Quarterly Compliance Report) (PPLPC019000195607) at slide 12 (Compliance Dept. resolution of 5 abuse/diversion inquiries); JX-1829 (1Q 2008 Quarterly Compliance Report) (PPLP004401169) at -171 ("Abuse & Diversion Detection (ADD) training – current"), and -186–87) (Compliance Dept. resolution of 1 abuse/diversion incident); JX-2655 (2Q 2008 Quarterly Compliance Report) (PPLP004401342) at -360–61 (Compliance Dept. resolution of 2 abuse/diversion incidents); JX-2656 (3Q 2008 Quarterly Compliance Report) (PPLP004402032) at -049–50 (Compliance Dept. resolution of 3 abuse/diversion inquiries), and -086 (detailed graphic explaining multiple ways Purdue conducts Sales Force Monitoring, including through mandatory reporting of indications of abuse or diversion, review of Field Contact Reports, and call note keyword searches); JX-2657 (4Q 2008 Quarterly Compliance Report) (PPLP004402205) at -224–25 (Compliance Dept. resolution of 4 abuse/diversion inquiries); JX-2658 (1Q 2009 Quarterly Compliance Report) (PPLP004402651) at -670–71 (Compliance Dept. resolution of 3 abuse/diversion inquiries); JX-2659 (2Q 2009 Quarterly Compliance Report) (PPLPC012000236639) at slides 18–19 (Compliance Dept. resolution of 2 abuse/diversion inquiries); JX-2661 (4Q 2009 Quarterly Compliance Report) (PPLP004403707) at -720–21 (Compliance Dept. resolution of 3 abuse/diversion inquiries); JX-2662 (1Q 2010 Quarterly Compliance Report) (PPLP004404102) at -114–15 (Compliance Dept. resolution of 5 abuse/diversion inquiries); JX-2663 (2Q 2010 Quarterly Compliance Report) (PPLP004404551) at -566–67 (Compliance Dept. resolution of 4 abuse/diversion inquiries); JX-2665 (4Q 2010 Quarterly Compliance Report) (PPLP004405709) at -718–19 (Compliance Dept. resolution of 3 abuse/diversion inquiries); JX-2666 (1Q 2011 Quarterly Compliance Report) (PPLP004406032) at -041–42 (Compliance Dept. resolution of 1 abuse/diversion inquiry); JX-2667 (2Q 2011 Quarterly Compliance Report) (PPLP004406466) at -480–81 (Compliance Dept. resolution of 1 abuse/diversion inquiry), and -486–90 (slide describing multiple methods of Sales Force Monitoring, followed by slides answering the question "How Does the Sales Monitoring 'System' Work in Practice?"); JX-2319 (Attachment to Oct. 25, 2011 Exec. Comm. Notes Sent to Board) (PURDUE-COR-0032186) at pp. 2–4, 11–13, 18 (defining diversion, Region 0 prescribers and the ADD Program, and presenting multiple charts reflecting substantial declines in diversion and prescriptions from Region 0 prescribers following introduction of abuse-deterrent formulation); JX-2669 (4Q 2011 Quarterly Compliance Report) (PPLP004407554) at -567–68 (Compliance Dept. resolution of 4 abuse/diversion inquiries); JX-1830 (Jul. 19, 2012 Quarterly Compliance Report) (PPLPUCC9002892662) at slide 18 (Compliance Dept. resolution of 1 abuse/diversion inquiry); JX-2673 (4Q 2012 Quarterly Compliance Report) (PPLP004409357) at -366 (Compliance Dept. resolution of 3 abuse/diversion inquiries); JX-1834 (Mar. 2017 Quarterly Compliance Report) (PPLP004413913) at -919–20 (describing enhanced monitoring and data mining of ADD Program); JX-2684 (June 2017 Quarterly Compliance Report) (PPLP004414244) at -248 (enhancement of ADD Program in progress).

[226] *See, e.g.*, JX-1828 (Feb. 8, 2008 Quarterly Compliance Report) (PPLPC019000195607) at slide 3 ("Purdue in compliance with AG Agreements ... Abuse & Diversion Detection (ADD) training - current"); JX-1829 (1Q 2008 Quarterly Compliance Report) (PPLP004401169) at -171

- District Managers were monitoring sales representatives' detailing of prescribers and preparing written reports (Field Contact Reports or "**FCRs**") assessing the sales reps' fulfillment of their ADD Program obligations.[227]

- Management was analyzing the FCRs and reporting to the Board the results of its analysis.[228]

("Purdue in compliance with AG Agreements[.] Abuse & Diversion Detection (ADD) training - current"); JX-2050 (3Q 2008 Board Report) (PPLP004367232) at -258 ("On September 26th, The Annual Report for First Reporting Period was submitted [to OIG], including ... Certification of all compliance training"); JX-2657 (4Q 2008 Quarterly Compliance Report) (PPLP004402205) at -226 ("National Sales Meeting[.] Well-received compliance workshops for all field personnel: Focused on ... Abuse & Diversion Detection (ADD) Program reporting requirements"); JX-2660 (3Q 2009 Quarterly Compliance Report) (PPLP004402982) at -986 ("Purdue is also in full compliance with its AG Agreements[.] Abuse & Diversion Detection (ADD) training - current"); JX-2661 (4Q 2009 Quarterly Compliance Report) (PPLP004403707), at -715 ("Purdue's National Sales Meeting.... Scenario-based Workshops 'owned' by all the District Managers[.] Focused on ... Abuse and Diversion Reporting"); JX-2664 (3Q 2010 Quarterly Compliance Report) (PPLP004405460) at -470–74 (extensive discussion of training on Purdue's Healthcare Law Compliance Policies, which require "Reports Pursuant to ADD Program" (*see, e.g.*, JX-2244 (Oct. 2007 Healthcare Law Compliance Policies) (PCA000008811) at -849)); JX-1830 (July 19, 2012 Quarterly Compliance Report) (PPLPUCC9002892662) at slide 10 ("Purdue committed to continue OxyContin Abuse and Diversion Detection Program.... Annual reminder and training to employees continues.").

[227] *See, e.g.*, JX-2047 (3Q 2007 Board Report) (PPLPC012000157402), at -460 ("With the Law Department, we trained all employees on the terms and obligations of the AG Agreements"); JX-1875 (7/30/08 Sales Force SOP) (PPLP003342665) at -689; JX-2272 (IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 2) (PPLP004433812), at -834–38; JX-2277 (9/25/09 Second Annual Report under CIA) (PPLPC063000000289); JX-2662 (1Q 2010 Quarterly Compliance Report) (PPLP004404102) at -106–07; JX-2291 (IRO's Report on Additional Promotional and Product Services Systems Assessment: Funding of Charitable Grants and Sponsorships, Reporting Period 3) (PPLP004434741) at -750–51; JX-1830 (2Q 2012 Quarterly Compliance Report) (PPLPUCC9002892662) at slide 3; JX-1881 (2013 Sales Force SOP) (PPLP003430093) at -131; JX-1884 (2016 Sales Force SOP Manual) (PPLP003578668) at -717. *See also, e.g.*, JX-2659 (2Q 2009 Quarterly Compliance Report) (PPLPC012000236639), at slide 3 (3 District Managers terminated for failing to monitor sales reps for sufficient number of days).

[228] *See, e.g.*, JX-1828 (Feb. 8, 2008 Quarterly Compliance Report) (PPLPC019000195607) at slide 6; JX-1829 (1Q 2008 Quarterly Compliance Report) (PPLP004401169) at -174; JX-2656 (3Q 2008 Quarterly Compliance Report) (PPLP004402032) at -039–40; JX-2657 (4Q 2008 Quarterly Compliance Report) (PPLP004402205) at -215–16; JX-2658 (1Q 2009 Quarterly Compliance Report) (PPLP004402651) at -663–64; JX-2659 (2Q 2009 Quarterly Compliance Report) (PPLPC012000236639) at slide 10; JX-2660 (3Q 2009 Quarterly Compliance Report)

- Compliance and Legal were monitoring sales call notes from sales representatives to ensure their adherence to the ADD Program.[229]

- Purdue's ADD Program and other anti-diversion efforts were effective in reducing and preventing abuse and diversion.[230]

(PPLP004402982) at -991; JX-2661 (4Q 2009 Quarterly Compliance Report) (PPLP004403707), at -712; JX-2662 (1Q 2010 Quarterly Compliance Report) (PPLP004404102) at -106; JX-2663 (2Q 2010 Quarterly Compliance Report) (PPLP004404551) at -554; JX-2664 (3Q 2010 Quarterly Compliance Report) (PPLP004405460) at -480–82; JX-2665 (4Q 2010 Quarterly Compliance Report) (PPLP004405709) at -713; JX-2666 (1Q 2011 Quarterly Compliance Report) (PPLP004406032) at -034, -036; JX-2667 (2Q 2011 Quarterly Compliance Report) (PPLP004406466), at -469, -483–84; JX-2674 (1Q 2013 Quarterly Compliance Report) (PPLP004409694) at -696–97; JX-2675 (3Q 2013 Quarterly Compliance Report) (PPLP004410506) at -512; JX-2677 (1Q 2014 Quarterly Compliance Report) (PPLP004411166) at -173. In addition, the CIA required that the IRO review and report on District Managers' monitoring of sales reps' interactions with prescribers during the CIA's second and fourth reporting years (from 8/1/08-7/31/09 and 8/1/10-7/31/11). *See* CIA §§III(D)(1)(b), III(D)(2), III(K) & Appendix B §§II(A)(7), II(B)(2). The IRO reviewed the monitoring system that Purdue put in place to assess compliance with the CIA. *See* JX-2272 (IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 2) (PPLP004433812), at -815, -833, -836, -837, -990; JX-2315 (IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 4) (PPLPC021000573227) at -245, -248–49; JX-2314 (IRO's Promotional and Product Services Transactions Engagement, Reporting Period 4) (PPLP004432560) at -604. The IRO's reports were forwarded to the OIG, as required by CIA §V(B)(5), and the OIG confirmed Purdue's compliance with the CIA. *See* JX-2691 (Second OIG Certification) (PPLP004250164); JX-1839 (Fourth OIG Certification) (PPLP004428603).

229 *See* JX-1871 (6/15/07 ADD SOP 1.7.1) (PPLP003429997); JX-1883 (Sept. 2015 ADD SOP 1.7.1) (PPLP004035073); JX-1888 (Aug. 2017 ADD SOP 1.7.1) (PPLPC016000316429).

230 *See, e.g.*, JX-2320 (Attachment to 10/25/11 Exec. Comm. Notes Sent to Board) (PURDUE-COR-00032185) at slide 14 (graph entitled "ORF [OxyContin Reformulated] Drug diversion events decline by 50%"); JX-2319 (Attachment to 10/25/11 Exec. Comm. Notes Sent to Board) (PURDUE-COR-00032186) at slide 11 (graph entitled "Among Region 0 prescribers the volume decreased for all formulations" showing substantial decline following introduction of the abuse-deterrent formulation); JX-2335 (6/18/12 Board Presentation) (PPLPC057000011194) at slide 9 (graph entitled "Four Drug Abuse/Diversion National Surveillance Systems" showing substantial declines in abuse and diversion following introduction of abuse-deterrent formulation); JX-2073 (Nov. 3, 2012 Presentation to Beneficiaries) (PPLP004409088) at -195 (slide entitled "Summary from Ongoing ORF [OxyContin Reformulated] Epidemiology Studies" reporting that evidence supports reduced abuse (consistent trend across studies) and reduced diversion and doctor-shopping); JX-2074 (Mar. 21, 2013 Board Agenda) (PPLPC044000041897) at -964 (graph entitled "Drug Diversion/Law Enforcement Events in RADARS System" showing substantial decline following introduction of abuse-deterrent formulation); *id.* at -961 (graph entitled "Abuse by

- In addition to the ADD Program, Purdue was addressing diversion by requiring field personnel to file Reports of Concern ("**ROCs**") reporting any alleged occurrences of misuse, abuse or diversion and then following up with field inquiries by management.[231]

Individual Assessed for Substance Abuse Treatment" showing substantial decline following introduction of abuse-deterrent formulation); *id.* at -962 (graph entitled Poison Center Data from National Poison Data System" showing substantial decline in abuse exposures following introduction of abuse-deterrent formulation); *id.* at -968 (slide entitled "Summary of Findings from Ongoing Epidemiology Studies" showing "Reduced diversion and 'doctor-shopping'" and "Reduced abuse relative to original OxyContin (consistent, durable)"); JX-2075 (July 25, 2013 Board Agenda) (PPLP004409781) at -860 (slide entitled "Positive Impact of AD OxyContin" stating "Meaningful Reduction in Abuse – Especially Parenteral"); JX-2381 (11/16/13 Presentation to Beneficiaries) (PPLPC051000193984) at -4069 (graph entitled "Change in Rates of Drug Diversion Events by Law Enforcement Agents" showing substantial decline following introduction of the abuse-deterrent formulation); *id.* at -4067 (table entitled "Reported abuse of OxyContin among abusers of any prescription opioid in the NAVIPPRO ASI-MV System (June 2009 – Dec 2012)" showing substantial decline in non-oral abuse of OxyContin following introduction of the abuse-deterrent formulation). *See also* JX-2324 (Nov. 2011 Summary of Findings of Post-Marketing Epidemiology Study Program) (PPLPC021000435532) at -585, Figure 11 ("OxyContin diversion cases over time from 1Q2002 to 2Q2011") showing substantial decline in OxyContin diversion following introduction of abuse-deterrent formulation).

[231] *See, e.g.*, JX-2047 (3Q 2007 Board Report) (PPLPC012000157402) at -437 ("46 field inquiries conducted [by Risk Management and Health Policy Dept.] in response to signals of abuse or diversion of OxyContin® as identified via review of ROCs, and RADARS® System data"); JX-2048 (4Q 2007 Board Report) (PPLP004367604) at -620 (Risk Management & Health Policy Dept. "Monitored Abuse and Diversion of PPLP Marketed Opioid Analgesics," reviewed "689 Reports of Concern (ROCs) regarding abuse and diversion of PPLP's marketed opioid analgesics" and conducted "21 field inquiries ... in response to signals of abuse or diversion of OxyContin® as identified via review of ROCs, and RADARS® System data"); JX-2049 (1Q 2008 Board Report) (PPLP004367134) at -149–50 (Risk Management & Health Policy Dept. "Monitored Abuse and Diversion of PPLP Marketed Opioid Analgesics," reviewed "853 ROCs regarding abuse and diversion of PPLP's marketed opioid analgesics" and conducted "17 field inquiries ... in response to signals of abuse or diversion of OxyContin as identified via review of ROCs, and RADARS® System data"); JX-2689 (2Q 2008 Board Report) (PPLP004367297) at -317 (Risk Management & Health Policy Dept. "Monitored Abuse and Diversion of PPLP Marketed Opioid Analgesics," reviewing "890 Reports of Concern (ROCs) regarding abuse and diversion of PPLP marketed opioid analgesics," and conducting "25 field inquiries ... in response to signals of abuse or diversion of OxyContin® as identified via review of ROCs, and RADARS® System data"); JX-2056 (1Q 2010 Board Report) (PPLP004317547) at -564 (Risk Management and Health Policy Dept. Involved in multiple "innovative programs that safeguard public health and address abuse and diversion of prescription medications"); JX-2674 (1Q 2013 Quarterly Compliance Report)

- Purdue was collaborating with wholesalers and national chains on order monitoring strategies.[232]

- Purdue's Order Monitoring System was a proactive program reducing the Company's risk.[233]

- Purdue's Suspicious Order Monitoring Committee was functioning well.[234]

- Purdue's anti-diversion received satisfactory compliance reviews by government entities.[235]

- In compliance with the 2007 Consent Judgments, in each of the years 2008, 2009 and 2010, Purdue (i) certified to the Consent Judgment States and D.C. that it had trained personnel on the ADD Program and (ii) reported the basic statistics on the ADD Program.[236]

(PPLP004409694) at -698 ("'Priority Risks'" that Compliance was "[a]ddressing in 2013" include "Drug diversion issues at clinical trial sites").

[232] *See, e.g.*, JX-2075 (7/25/13 Board Agenda) (PPLP004409781) at -866.

[233] *See, e.g.*, Nov. 2011 Board Budget Presentation for 2012 (PPLPUCC003392177) at p. 400 ("Proactive Programs – Reducing Risks in 2011 and Beyond ... ▪ Order Monitoring Program (OMS)"). The Order Monitoring System and Abuse and Diversion Detection Program shared information, "[r]esult[ing] in more robust information to share with internal (e.g., Risk Management) and external (e.g., authorized distributors) partners." *See* July 21, 2010 Order Monitoring System ("OMS Program") Presentation to Corporate Compliance Council (PPLP004436879) at slide 6.

[234] *See, e.g.*, June 15, 2017, Board Agenda (Ethics and Compliance Update) (PPLPC018001437163) at -200.

[235] *See, e.g.*, JX-2069 (1/21/10 Board Agenda) (PPLPC044000023970) at -4003–05 (reporting "Losses in Transit – 0," successful "DEA 'Inspections/Audits'" and "Investigations Program" accomplishments in "Diversion (all Products) – Doctor Shopping/False Rx"); JX-2058 (3Q 2010 Board Report) (PPLP004366991) at -998 ("DEA closed out the product diversion investigation which had been opened since early 2010"); JX-2323 (2012 Budget Presentation to the Board) (PPLPUCC9011086649) at slide 5 ("Bottle Tracking Program: ● Agreements with 14 United States Attorneys' Offices and Boards of Pharmacy ● Discussions with Department of Justice on national agreement"); *id.* at slide 6 ("DEA feedback on ORF [OxyContin Reformulated] ● Statements of Barbara Boockholdt, Chief, Regulatory Section, DEA, Office of Diversion Control ▪ ORF has made a tremendous difference ▪ No longer hear about OxyContin from field offices ▪ORF is saving lives").

[236] Ky. Consent Judgment ¶24(c) and (e); *See* JX-2257 (5/7/08 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance) (PPLPC026000041921). *See also* JX-2266 (5/7/09 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance)

144. The SOM and OMS programs, and multiple other Purdue Departments' roles in anti-diversion activities, as reported to the Board, are discussed below.

145. Not only did the Board properly rely on reports from management that the ADD Program and other anti-diversion programs and procedures were in place and working,[237] the Board also authorized the expenditure of more than $1 billion on Purdue's anti-diversion efforts,[238] including primarily on the development of the abuse-deterrent formulation of OxyContin. Reports to the Board continually affirmed the success of these efforts in reducing and preventing abuse.

A. Purdue's Anti-Diversion Programs

1. The ADD Program

146. Purdue's ADD Program, which it voluntarily implemented in 2002, was the first of its kind in the industry.

147. The ADD Program was "designed to ensure that the company [did] not promote Purdue's products in circumstances where there [was] a concern about potential abuse or diversion related activities."[239]

(PWG004407107); JX-2284 (5/7/10 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance) (PPLPC026000064681).

[237] N.Y. BUS. CORP. LAW §717 ("In performing his duties, a director shall be entitled to rely on information, opinions, reports or statements … prepared or presented by … officers or employees of the corporation … whom the director believes to be reliable and competent in the matters presented ….").

[238] *Select Initiatives Addressing the Crisis*, PURDUE PHARMA, https://www.purduepharma.com/addressing-the-crisis/select-initiatives/ (stating that "Purdue has spent approximately $1 billion to develop opioids with abuse-deterrent properties" and identifying other anti-diversion efforts by Purdue) (last visited July 16, 2021).

[239] JX-2321 (Changes in Prescribing Patterns Following Introduction of Reformulated OxyContin: A Window into Diversion) (PPLPC042000024694) at slide 3.

148. The ADD Program relied on the information Purdue had available to it—observations made by its sales representatives, reports made by District Managers and third parties, publicly available information, and prescription data that Purdue purchased from third parties—to help Purdue identify potentially problematic prescribers, so that it could stop promoting to them.[240]

a. ADD Reports

149. The ADD Program required that every ADD Covered Person (basically, everyone in contact with HCPs and pharmacists)[241] file an ADD Report promptly after s/he "learn[ed] of a circumstance or makes an observation that may be indicative of potential abuse or

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[240] *See, e.g.*, JX-2263 (11/19/08 Memo from Law Department Summarizing Investigation) (PPLPUCC9011223777) (investigation of prescriber relied on: information from Purdue sales representative and district manager, state medical board website, call reports, and prescription history from third-party, IMS Health); JX-2357 (Aug. 30, 2013 Memo from Law Department Summarizing Investigation) (PPLPUCC9011223702) (investigation of prescriber relied on: information from Purdue sales representative, state medical board website, call reports, prescription history from third-party, IMS Health, and Purdue contract and key opinion leader ("**KOL**") databases). The ADD Program charged Purdue's Law Department with the responsibility to make a determination about whether to refer an HCP to the DEA or other regulatory authorities. *See* JX-2432 (Feb. 5, 2016 ADD Program Working Practice Document) (POK003723668) at ¶5.D.2.b. *See also* JX-2259 (Internal Inquiries: Procedures) (PPLPC019000213919) at -320 ("The General Counsel's Office will take whatever steps are deemed appropriate, including but not limited to, notifying regulatory or law enforcement authorities of Purdue's concern about the conduct of a particular healthcare professional or other person."); JX-2457 (Jan. 25, 2018 ADD Program Working Practices Document) (PPLPC023000971903) at ¶5.C.5.

[241] *See* JX-1883 (Sept. 2015 ADD SOP 1.7.1) (PPLP004035073) at -073 (defining "ADD Covered Persons" to include "all members of Purdue's field sales organization, medical science liaisons and other Purdue employees and contract or third party sales representatives who contact practicing Prescribers or Pharmacists … for the purpose of promoting a Purdue opioid product"). While the term "ADD Covered Persons" was not used in 6/15/07 ADD SOP 1.7.1, the same personnel had the same reporting obligations. *See* JX-1871 (6/15/07 ADD SOP 1.7.1) (PPLP003429997) at -997 (definition of "Individuals With Reporting Obligations").

diversion."[242]

150. The ADD Program specified objective triggers that required a report, including atypical prescribing habits; excessive numbers of patients; credible allegations of diversion, abuse, or patient overdose; unauthorized prescription signing or dispensing; and investigation by authorities.[243]

151. Information obtained during sales calls was reported through Purdue's call note system or to Drug Safety & Pharmacovigilance and was forwarded to the Law Department, and ADD Forms were available to submit to the Law Department.[244]

b. Various Departments Had Roles in the ADD Program

152. Prior to mid-2016, the Law Department oversaw the ADD Program (the applicable SOP 1.7.1 was issued by the Law Department), but other departments were also involved.

153. The Law Department worked in conjunction with the Compliance, Sales, Sales

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[242] JX-1871 (6/15/07 ADD SOP 1.7.1) (PPLP003429997) at -997; JX-1883 (Sept. 2015 ADD SOP 1.7.1) (PPLP004035073) at -075; JX-1888 (Aug. 2017 ADD SOP 1.7.1) (PPLPC016000316429) at -431.

[243] JX-1871 (6/15/07 ADD SOP 1.7.1) (PPLP003429997) at -998–99. The 2002 ADD Program contained 11 specified triggers, but Purdue revised the Program in October 2003 and again in 2007 to add additional triggers. *Compare* JX-1864 (11/1/02 ADD SOP 1.7.1) (PPLP003430434) at -434–35 *with* JX-1867 (10/6/03 ADD SOP 1.7.1) (PDD1503493410) and JX-1871 (6/15/07 ADD SOP 1.7.1) (PPLP003429997) at 998–99. Purdue added another two triggers to the ADD Program in 2015, and amended the SOP to declare the purpose of the program to be "preclud[ing] promotion of Purdue's opioid products in circumstances where there is a concern about potential abuse or diversion related to a particular Prescriber, Pharmacist, his/her patients or opioid products" in connection with the Assurance of Discontinuance Purdue entered into with the State of New York. *Compare* JX-1871 (6/15/07 ADD SOP 1.7.1) (PPLP003429997) at 998–99 *with* JX-1883 (Sept. 2015 ADD SOP 1.7.1) (PPLP004035073) at -073–74). *See also* AOD at ¶29(a) and (b).

[244] JX-1871 (6/15/07 ADD SOP 1.7.1) (PPLP003429997) at -999; JX-2457 (Jan. 25, 2018 ADD Program Working Practices Document) (PPLPC023000971903) at ¶5.C.

Operations, and Human Resources Departments to develop and maintain procedures to assist ADD Covered Persons in reporting observations or circumstances that raised concerns about abuse, diversion, or inappropriate prescribing of opioids, and in conducting the review and follow-up generated by those reports.[245]

154. The Law Department, consistent with ADD SOP, investigated each ADD Report to determine whether to place the prescriber on the Purdue's No Call list—commonly referred to as Region Zero.[246]

155. If the Law Department placed a prescriber in Region Zero, sales reps were prohibited from calling on (detailing) that prescriber and would not earn any sales incentive bonus based on prescriptions that prescriber wrote.[247]

156. The Compliance Department forwarded to the Law Department all call notes raising ADD Program concerns.[248]

157. The Compliance Department also performed compliance risk assessments, seeking to limit exposure through a variety of actions, including policies, SOPs, training, and

[245] JX-2432 (Feb. 5, 2016 ADD Program Working Practices Document) (POK003723668) at ¶4.

[246] *See* JX-2259 (Internal Inquiries: Procedures) (PPLPC019000213919) ("In each instance in which the General Counsel's office receives notification of a sales representative's or other field personnel's concern about a healthcare professional's conduct that may indicate abuse or diversion of OxyContin or other controlled substances distributed by Purdue, the General Counsel's office will follow the procedures outlined below.").

[247] *See* JX-1871 (6/15/07 ADD SOP 1.7.1) (PPLP003429997) at -30000; JX-1883 (Sept. 2015 ADD SOP 1.7.1) (PPLP004035073) at -076; JX-1888 (Aug. 2017 ADD SOP 1.7.1) (PPLPC016000316429) at -432.

[248] JX-2432 (Feb. 5, 2016 ADD Program Working Practices Document) (POK003723668) at ¶5.C (fourth bullet point).

auditing and monitoring.[249]

158. The Sales Operations Department conducted periodic reviews of prescription and other data to identify potential abuse, diversion or inappropriate prescribing of opioids and referred identified prescribers to the Law Department for review.[250]

159. All other departments were obligated to forward to the Law Department any information they had raising concerns about a prescriber's potential abuse, diversion or inappropriate prescribing of opioids.[251]

160. In mid-2016, the Compliance Department assumed a larger role in oversight and implementation of the ADD Program.[252]

161. It began performing the initial review, evaluation and follow-up of ADD Reports.[253]

162. The Compliance Department forwarded to the Law Department all ADD Reports that were "not automatic 'no call' determinations"—that is, did not automatically result in the Compliance Department placing the prescriber on the Region Zero list—and the Law Department then coordinated investigations with outside counsel to determine whether the

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[249] JX-2432 (Feb. 5, 2016 ADD Program Working Practices Document) (POK003723668) at ¶5.C (fourth bullet point).

[250] JX-2432 (Feb. 5, 2016 ADD Program Working Practices Document) (POK003723668) at ¶5.C (third bullet point).

[251] JX-2667 (Quarterly Compliance Report 2Q 2011) (PPLP004406466) at -471–72.

[252] *See* JX-1833 (Aug. 25, 2016 Ethics and Compliance Quarterly Report) (PPLPUCC003271544) at -545. *See also* JX-1888 (Aug. 2017 ADD SOP 1.7.1) (PPLPC016000316429) at -431 and JX-2457 (Jan. 25, 2018 ADD Program Working Practices Document) (PPLPC023000971903) for the respective roles of the Law and Compliance Departments.

[253] *See* JX-1888 (Aug. 2017 ADD SOP 1.7.1) (PPLPC016000316429) at -431.

prescriber should be placed in Region Zero.[254]

c. Prescriber News Alerts

163. As part of the ADD Program, Purdue monitored media sources daily for "news stories concerning adverse criminal or licensing actions taken against HCPs nationwide."[255]

164. The Law Department, and later the Compliance Department, was responsible for reviewing "News Alerts" and, where appropriate, updating HCP profiles within the ADD system to record any news alert that triggered a further review of a given HCP.[256]

d. Data Review

165. The Sales Operation Department had an independent obligation under the ADD Program to "conduct [a] ... periodic review of sales prescription and other data sources to identify potential abuse, diversion or inappropriate prescribing of opioids" and then to "refer[] prescribers who are identified to the ADD Legal Mailbox for review," among its other ADD Program roles.[257]

166. The Sales and Human Resources Departments worked with the Compliance and Law Departments to develop and maintain internal procedures to assist ADD Covered Persons in reporting observations or circumstances that suggested potential concerns about abuse, diversion,

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[254] *Id*.

[255] JX-2432 (Feb. 5, 2016 ADD Program Working Practices Document) (POK003723668) at ¶5.C (second bullet point); JX-2457 (Jan. 25, 2018 ADD Program Working Practices Document) (PPLPC023000971903) at ¶¶4, 5.C.2.

[256] JX-2432 (Feb. 5, 2016 ADD Program Working Practices Document) (POK003723668) at ¶5.C (second bullet point); JX-2457 (Jan. 25, 2018 ADD Program Working Practices Document) (PPLPC023000971903) at ¶6.

[257] JX-2457 (Jan. 25, 2018 ADD Program Working Practices Document) (PPLPC023000971903) at ¶¶4, 5.C.3, 6.C.1, 6.H.1; JX-2432 (Feb. 5, 2016 ADD Program Working Practices Document) (POK003723668) at ¶5.C (third bullet point).

or inappropriate prescribing of opioids, and to conduct the review and follow up generated by those reports.[258]

e. Call Note and Hotline Review—ADD Program and Other Compliance Obligations

167. Sales representatives were required to record in Purdue's call note system any "concerns about compliance or potential abuse issues" learned on calls with prescribers and pharmacists.[259]

168. The Compliance Department was also charged with responsibility for identifying to the Law Department "any call notes that raise potential concerns related to compliance with the ADD Program" and summaries of "any contacts to the Ethics & Compliance Hotline that raise ADD Concerns."[260]

f. Corporate Security, Medical Information and IT Departments

169. The ADD Program required that Purdue's Corporate Security Department and Medical Information Department forward to the Legal Department "any information which those departments may gather that raise concerns about a prescriber's potential abuse, diversion or

[258] JX-2432 (Feb. 5, 2016 ADD Program Working Practices Document) (POK003723668) at ¶4; JX-2457 (Jan. 25, 2018 ADD Program Working Practices Document) (PPLPC023000971903) at ¶¶4, 6.H.1.

[259] *See* JX-1883 (Sept. 2015 ADD SOP 1.7.1) (PPLP004035073) at-075; JX-1888 (Aug. 2017 ADD SOP 1.7.1) (PPLPC016000316429) at -432.

[260] JX-2432 (Feb. 5, 2016 ADD Program Working Practices Document) (POK003723668) at ¶5.C (fourth bullet point). *See also* JX-2457 (Jan. 25, 2018 ADD Program Working Practices Document) (PPLPC023000971903) at ¶5.C.4; JX-1883 (Sept. 2015 ADD SOP 1.7.1) (PPLP004035073) at -075; JX-1888 (Aug. 2017 ADD SOP 1.7.1) (PPLPC016000316429) at -432.

inappropriate prescribing of opioids."[261]

170. The IT Department supported the ADD Program by enhancing the Phoenix customer contact system—which sales representatives used to record their call notes—"to make compliance easier, less time consuming, and more auditable."[262]

g. ADD Program Training

171. ADD Covered Persons were required to "receive training on the ADD Program on an annual basis;" newly hired or transferred employees were required to be trained "on the ADD Program as part of their new hire training;" and trained employees received "annual online training pursuant to an Online Workplace Learning (OWL) module disseminated by Purdue's Ethics & Compliance Department."[263]

h. Discipline for Violations of ADD Program Duties

172. The ADD Program authorized the Law Department to take a range of disciplinary actions against any employee who violated the ADD Policy, including "written warning, probation, bonus ineligibility, or termination of employment."[264]

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[261] JX-2432 (Feb. 5, 2016 ADD Program Working Practices Document) (POK003723668) at ¶5.C (fifth bullet point); JX-2457 (Jan. 25, 2018 ADD Program Working Practices Document) (PPLPC023000971903) at ¶5.C.5.

[262] JX-2046 (July 17, 2007 Quarterly Report to the Board) (PPLP004366645) at -694.

[263] JX-2432 (Feb. 5, 2016 ADD Program Working Practices Document) (POK003723668) at ¶5.B; *see also* JX-2457 (Jan. 25, 2018 ADD Program Working Practices Document (PPLPC023000971903) at ¶5.B. The Compliance Department was renamed the Ethics and Compliance Department in late 2015. *See* JX-2682 (3Q 2015 Quarterly Ethics and Compliance Report) (PPLP004412546) at -548.

[264] JX-1883 (Sept. 2015 ADD SOP 1.7.1) (PPLP004035073) at-076; JX-1888 (Aug. 2017 ADD SOP 1.7.1) (PPLPC016000316429) at-432.

2. **Adverse Event Reporting**

173. In addition to the ADD Program, pursuant to FDA regulations, Purdue reported to the FDA "all adverse drug experience [and] information" associated with its products, "including information derived from commercial marketing experience."[265]

174. Purdue implemented procedures to ensure that all Purdue Employees[266] reported any "Adverse Event ... occur[ring] during the course of the drug's use in professional practice, as well as from a drug overdose, whether accidental or intentional, drug abuse, [or] [d]rug withdrawal."[267]

175. The Adverse Event reporting obligation was not limited to Purdue's opioid medications but extended to other products, including laxatives, Betadine (surgical solution), Slow-Mag (magnesium) tablets, and all branded or generic products "with the same chemical entity as one of [Purdue's] products."[268]

176. Sales representatives and other Employees were required to report Adverse

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[265] *See* 21 C.F.R. §314.80(b) ("each applicant having an approved application … must promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source … including information derived from commercial marketing experience …").

[266] *See* JX-1868 (MA-DSP-SOP-000001) (PPLPUCC002500202) (defining "Employee" as any "Person employed by one of more of the Associated US Companies ... or agents, consultants, licensees and/or distributors retained by the Associated US Companies").

[267] JX-2246 (2008 Training Materials) (PPLP003550586) at -594. *See also* JX-1868 (MA-DSP-SOP-000001) (PPLPUCC002500202) at ¶3 (defining "Adverse Event" as "[a]ny adverse event associated with the use of a drug (or biological product) in humans, whether or not considered drug/product related," including "in the course of the use of a drug/product in professional practice," "from drug overdose whether accidental or intentional," "from drug abuse," "from drug withdrawal," and "any failure of expected pharmacological actions"); JX-2226 (8/22/05 Sales Training and Development re: Reporting of Adverse Events) (PDD1503520499); JX-1869 (MA-DSP-SOP-000002-Postmarketing Adverse Event Capture and Reporting) (PPLP004392219).

[268] JX-2246 (2008 Training Materials) (PPLP003550586) at -600–03.

Events to Purdue's Drug Safety Operations team within its Drug Safety & Pharmacovigilance Department, who, together with Purdue's Law Department, would determine the severity of the issue and appropriate follow up.[269]

177. "Vice Presidents and respective senior management members at all company sites" were "responsible for instituting [the Adverse Events SOP] among their Employees" and ensuring employee training.[270] Purdue management regularly reported to the Board on Adverse Event training and reporting.[271]

3. **Reports of Concern**

178. In addition to the ADD Program, Purdue required Field Personnel[272] to file

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[269] JX-2246 (2008 Training Materials) (PPLP003550586) at -609–12, -644. *See also* JX-1868 (MA-DSP-SOP-000001) (PPLPUCC002500202) at ¶¶1.1, 4.2.

[270] JX-1868 (MA-DSP-SOP-000001) (PPLPUCC002500202) at ¶4.2.

[271] *See, e.g.*, JX-2046 (2Q 2007 Board Report) (PPLP004366645) at -685–687, -693; JX-2047 (3Q 2007 Board Report) (PPLPC012000157402) at -437; JX-2048 (4Q 2007 Board Report) (PPLP004367604) at -620; JX-2689 (2Q 2008 Board Report) (PPLP004367297) at -320; JX-2655 (2Q 2008 Quarterly Compliance Report) (PPLP004401342) at -357; JX-2050 (3Q 2008 Board Report) (PPLP004367232) at -249; JX-2656 (3Q 2008 Quarterly Compliance Report) (PPLP004402032) at -062; JX-2657 (4Q 2008 Quarterly Compliance Report) (PPLP004402205) at -226; JX-2664 (3Q 2010 Quarterly Compliance Report) (PPLP004405460) at -470–72; JX-2705 (2Q 2011 Board Report) (PPLP004366913) at -930–931; JX-2667 (2Q 2011 Quarterly Compliance Report) (PPLP004406466) at -485; JX-2063 (2Q 2012 Board Report) (PPLPC012000387069) at -089; JX-2672 (3Q 2012 Quarterly Compliance Report) (PPLP004408439) at -454; JX-2679 (4Q 2014 Quarterly Compliance Report) (PPLP004411811) at -816; JX-2682 (3Q 2015 Quarterly Compliance Report) (PPLP004412546) at -550, -554; JX-1833 (Aug. 25, 2016 Ethics and Compliance Report) (PPLPUCC003271544); JX-1834 (Mar. 2017 Ethics & Compliance Report) (PPLP004413913) at -922; JX-2684 (June 2017 Ethics & Compliance Report) (PPLP004414244) at -248.

[272] "Field Personnel" included "Field Sales Representatives, District Managers, Regional Managers, National Account Managers, Account Executives, Law Enforcement Education and Liaisons, Medical Liaisons, RADARS System Field Researchers, and any other individual with field-related activities." JX-1870 (RM-SOP-000001-Routing of Reports of Concern regarding PPLP Marketed Opioid Analgesics by Field Personnel) (PPLPC039000340008) at ¶3.

ROCs—reports of "an alleged occurrence of misuse, abuse or diversion of a Purdue Marketed Opioid Analgesic" other than an Adverse Event[273]—with the Drug Safety & Pharmacovigilance Department.[274]

179. The ROC SOP allocated responsibility for implementation of the policy to:

a. Vice Presidents (to institute the SOP and ensure training of all personnel);

b. Field Personnel (to file ROCs); to Purdue's Drug Safety & Pharmacovigilance Department (to receive and route all ROCs to the Risk Management & Health Policy Department); and

c. The Risk Management & Health Policy Department (to log, verify, confirm and analyze all information received as an ROC and to route to the Drug Safety & Pharmacovigilance Department for any ROCs determined to constitute an Adverse Event).[275]

180. The Risk Management & Health Policy reported to the Board that it was "Monitor[ing] Abuse and Diversion of PPLP's Marketed Opioid Analgesics," reviewing ROCs and conducing field inquiries.[276]

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[273] JX-2246 (2008 Training Materials) (PPLP003550586) at -624; JX-1870 (RM-SOP-000001-Routing of Reports of Concern regarding PPLP Marketed Opioid Analgesics by Field Personnel) (PPLPC039000340008) at ¶¶2.3, 3.

[274] JX-2246 (2008 Training Materials) at PPLP003550586) at -624; JX-1870 (RM-SOP-000001-Routing of Reports of Concern regarding PPLP Marketed Opioid Analgesics by Field Personnel) (PPLPC039000340008).

[275] JX-1870 (RM-SOP-000001-Routing of Reports of Concern regarding PPLP Marketed Opioid Analgesics by Field Personnel) (PPLPC039000340008) at ¶¶3, 4.

[276] *See* JX-2046 (2Q 2007 Board Report) (PPLP004366645) at -677 ("572 Reports of Concern (ROCs) regarding abuse and diversion of PPLP marketed opioid analgesics logged for 2nd Quarter 2007 and 21 field inquiries completed" by Risk Management); JX-2047 (3Q 2007 Board Report) (PPLPC012000157402) at -437 ("46 field inquiries conducted [by Risk Management and Health Policy Dept.] in response to signals of abuse or diversion of OxyContin® as identified via review of ROCs, and RADARS® System data"); JX-2048 (4Q 2007 Board Report) (PPLP004367604) at -620 (Risk Management & Health Policy Dept. "Monitored Abuse and Diversion of PPLP Marketed Opioid Analgesics," reviewed "689 Reports of Concern (ROCs) regarding abuse and diversion of PPLP marketed opioid analgesics" and conducted "21 field inquiries ... in response to

4. The Suspicious Order Monitoring Program and Order Monitoring System

181. Purdue implemented the Suspicious Order Monitoring Program in 2003 to ensure compliance with DEA regulations[277] and voluntarily developed the Order Monitoring System in 2008 as a supplemental DEA compliance program.[278]

182. **SOM Program.** The SOM Program required that members of Purdue's controlled substances team in Customer Service "review each order for unusual qualities or any other deviation from the customer's regular order pattern."[279]

183. All suspicious orders had to be reported to Senior Directors at Purdue, who were tasked with "contact[ing] the customer to obtain additional information," and "provid[ing] the Associate General Counsel with all of the information gathered." [280]

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signals of abuse or diversion of OxyContin® as identified via review of ROCs, and RADARS® System data"); JX-2049 (1Q 2008 Board Report) (PPLP004367134) at -149–50 (Risk Management & Health Policy Dept. "Monitored Abuse and Diversion of PPLP Marketed Opioid Analgesics," reviewed "853 ROCs regarding abuse and diversion of PPLP marketed opioid analgesics" and conducted "17 field inquiries ... in response to signals of abuse or diversion of OxyContin as identified via review of ROCs, and RADARS® System data"); JX-2689 (2Q 2008 Board Report) (PPLP004367297) at -317 (Risk Management & Health Policy Dept. "Monitored Abuse and Diversion of PPLP Marketed Opioid Analgesics," reviewing "890 Reports of Concern (ROCs) regarding abuse and diversion of PPLP marketed opioid analgesics," conducting "25 field inquiries ... in response to signals of abuse or diversion of OxyContin® as identified via review of ROCs, and RADARS® System data"); JX-2056 (1Q 2010 Board Report) (PPLP004317547) at -564 (Risk Management and Health Policy Dept. Involved in multiple "innovative programs that safeguard public health and address abuse and diversion of prescription medication"); JX-2674 (1Q 2013 Quarterly Compliance Report) (PPLP004409694) at -698 ("'Priority Risks'" that Compliance was "[a]ddressing in 2013" include "Drug diversion issues at clinical trial sites."

277 *See* JX-1865 (3/12/03 SOM SOP) (PPLPC035000019501).

278 *See* JX-2288 (07/21/10 Presentation to Corporate Compliance Council entitled "The Order Monitoring System") (PPLPC041000011499).

279 JX-1865 (3/12/03 SOM SOP) (PPLPC035000019501) at -501.

280 *Id.* at -502.

184. The SOM SOP then required Purdue's Law Department to "determine if further investigative steps [were] required and if the findings should be reported to the Field Office of the DEA." [281]

185. **OMS Program.** The OMS Program was designed to "enhance ... systems, review and vigilance in the area of suspicious order monitoring."[282]

186. Purdue's customers were not patients or HCPs—they were authorized distributors of Purdue's products, and each of them had an independent duty under federal law to monitor for suspicious orders made by their customers—pharmacies.

187. The goal of the OMS Program was "to support [Purdue's] authorized distributors in their efforts in the area of Suspicious Order Monitoring."[283]

188. OMS relied primarily on data Purdue purchased from authorized distributors to identify potentially problematic pharmacies.[284]

189. Under the OMS SOP, an interdisciplinary group—from the Office of the General Counsel, CSA Compliance, National Accounts and Corporate Security—reviewed all accounts that exhibited abnormal behavior and determined whether Purdue should discuss an account with the authorized distributor or refer the account to the DEA.[285]

190. [Intentionally deleted]

191. [Intentionally deleted]

192. [Intentionally deleted]

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281 *Id.*

282 JX-1876 (3/23/09 OMS SOP) (PPLPUCC9011108993).

283 JX-2302 (4/12/11 email from Jack Crowley to Burt Rosen) (PPLPC053000051168).

284 JX-1876 (3/23/09 OMS SOP) (PPLPUCC9011108993).

285 *Id.* at -995.

193. [Intentionally deleted]

194. [Intentionally deleted]

5. <u>Manufacturing and Supply Chain Anti-Diversion Duties</u>

195. In addition to the ADD, OMS, and SOM Programs, the Board was informed that Manufacturing & Supply Chain was tasked with "[a]ssur[ing] compliance with all FDA, DEA, OSHA and EPA laws and regulations" in connection with the supply of Purdue pharmaceuticals.[286]

196. Manufacturing & Supply Chain reported to the Board that it accomplished this "by auditing, monitoring key metrics and planned system upgrades/improvements (FDA, DEA, OSHA and EPA, CIA and HR policy)."[287]

B. The Former Directors Responsibly Monitored Purdue's <u>ADD Program and Other Anti-Diversion Measures</u>

197. The PPI Board responsibly monitored Purdue's anti-diversion efforts through extensive management presentations.

198. Management presentations to the Board explained the systems in place for

[286] *See, e.g.*, JX-2055 (4Q 2009 Board Report) (PPLP004367162) at -184; JX-2056 (1Q 2010 Board Report) (PPLP004317547) at -552; JX-2057 (2Q 2010 Board Report) (PPLP004367018) at -024; JX-2058 (3Q 2010 Board Report) (PPLP004366991) at -996; JX-2059 (4Q 2010 Board Report) (PPLP004366955) at -963; JX-2692 (1Q 2011 Board Report) (PPLPC012000322426) at -436; JX-2705 (2Q 2011 Board Report) (PPLP004366913) at -928; JX-2060 (3Q 2011 Board Report) (PPLP004366871) at -885; JX-2061 (4Q 2011 Board Report) (PPLPC012000362869) at -885.

[287] *See, e.g.*, JX-2062 (1Q 2012 Board Report) (PPLPC012000374791) at -802; JX-2063 (2Q 2012 Board Report) (PPLPC012000387069) at -087; JX-2064 (3Q 2012 Board Report) (PPLP004366816) at -847; JX-2065 (4Q 2012 Board Report) (PPLP004366760) at -790; JX-2693 (1Q 2013 Board Report) (PPLP004367540) at -576; JX-2066 (2Q 2013 Board Report) (PPLPC012000433388) at -418; JX-2067 (3Q 2013 Board Report) (PPLPC002000186911) at -941; JX-2068 (4Q 2013 Board Report) (PPLPC002000181035) at -059.

Compliance Reporting—including reporting of "Adverse events, product complaints, [and] [i]ndications of abuse or diversion [that were] recorded in call system and automatically sent to Drug Safety & Pharmacovigilance Department."[288]

199. The Board was informed that these reporting systems, as well as reports from a variety of other Purdue sources—including the "Hotline," "Field Contact Reports," other "disclosure programs," "[m]atters found during other compliance activities," "[c]all notes," and "[p]otential compliance or regulatory matters forwarded to Corporate Compliance for Review"—generated "Investigations" by Purdue's Compliance Department.[289]

200. The Board was advised that "Region 0 prescribers" were identified through the ADD Program "to ensure that the company does not promote Purdue's products in circumstances where there is a concern about potential abuse or diversion related activities."[290]

201. The Board was continually advised in reports from management that it was implementing the ADD and other anti-diversion programs.

202. The Board received regular updates on the types of compliance issues that came to Purdue's attention through internal reporting sources governed by the ADD Program and the Adverse Event and ROC reporting, as well as through Purdue's call notes and hotline.

203. The Compliance Department reported, for example, on the number of inquiries it received for investigation, how many related to abuse or diversion matters[291] and how long each

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[288] JX-2656 (3Q 2008 Quarterly Compliance Report) (PPLP004402032) at -086.

[289] *Id*.

[290] JX-2319 (Attachment to Oct. 25, 2011 Exec. Comm. Notes Sent to Board) (PURDUE-COR-0032186) at p. 3.

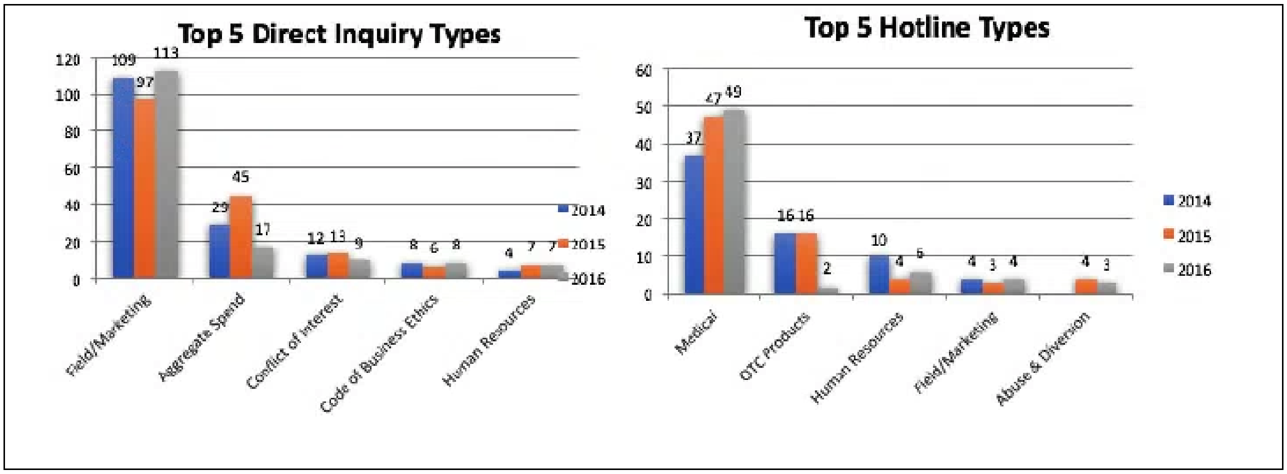
[291] *See, e.g.*, JX-1827 (Aug. 6, 2007 Quarterly Compliance Report) (PPLP004399954) at -968 ("101 inquiries in Q2 2007," with "2 Abuse, Diversion Matters … pursuant to RSOP 1.7.1"); JX-

quarter's inquiries took to close.[292]

1828 (Feb. 8, 2008 Quarterly Compliance Report) (PPLPC019000195607) at slides 8, 12 ("86 inquiries in 4Q07," with 5 related to ADD); JX-1829 (1Q 2008 Quarterly Compliance Report) (PPLP004401169) at -183, -186 ("95 matters in 1Q08," with 1 related to ADD); JX-2655 (2Q 2008 Quarterly Compliance Report) (PPLP004401342) at -357, -360 ("106 matters in 2Q08," with 2 related to ADD); JX-2656 (3Q 2008 Quarterly Compliance Report) (PPLP004402032) at -046, -049 ("163 matters in 3Q08," with 3 related to ADD); JX-2657 (4Q 2008 Quarterly Compliance Report) (PPLP004402205) at -222, -224 ("130 matters in 4Q08," with 4 related to ADD); JX-2658 (1Q 2009 Quarterly Compliance Report) (PPLP004402651) at -668, -670 ("125 matters in 1Q09," with 3 related to ADD); JX-2659 (2Q 2009 Quarterly Compliance Report) (PPLPC012000236639), at slides 16, 18 ("192 matters in 2Q09," with 2 related to ADD); JX-2660 (3Q 2009 Quarterly Compliance Report) (PPLP004402982) at -996, -998 ("133 'matters' in 3Q09," with 1 related to ADD); JX-2661 (4Q 2009 Quarterly Compliance Report) (PPLP004403707) at -718, -720 ("125 'matters' in 4Q09," with 3 related to ADD); JX-2662 (1Q 2010 Quarterly Compliance Report) (PPLP004404102) at -112, -114 ("130 'matters'" with 5 related to ADD); JX-2663 (2Q 2010 Quarterly Compliance Report) (PPLP004404551) at -564, -566 ("134 'matters' in 2Q10," with 4 related to ADD); JX-2665 (4Q 2010 Quarterly Compliance Report) (PPLP004405709) at -716, -718 ("200 matters in 4Q10," with 3 related to ADD); JX-2666 (1Q 2011 Quarterly Compliance Report) (PPLP004406032), at -039, -041 ("88 matters in 1Q2011," with 1 related to ADD); JX-2667 (2Q 2011 Quarterly Compliance Report) (PPLP004406466) at -478; *id*. at -480 ("106 matters in 2Q2011," with 1 related to ADD); JX-2669 (4Q 2011 Quarterly Compliance Report) (PPLP004407554) at -564, -567 ("74 matters in 4Q11," with 4 related to ADD); JX-1830 (2Q 2012 Quarterly Compliance Report) (PPLPUCC9002892662) at 18 (57 matters in 2Q2012, with 1 related to ADD); JX-2673 (4Q 2012 Quarterly Compliance Report) (PPLP004409357) at -366 (identifying 3 ADD issues for the "Full Year 2012").

[292] *See, e.g.*, JX-1827 (Aug. 6, 2007 Quarterly Compliance Report) (PPLP004399954) at -971 (most resolved within 7 days, and all within 60 days); JX-1828 (Feb. 8, 2008 Quarterly Compliance Report) (PPLPC019000195607) at 13 (65 resolved within 7 days, 9 outstanding after 90 days); JX-1829 (1Q 2008 Quarterly Compliance Report) (PPLP004401169) at -187 (60 resolved with 7 days, and all within 90 days); JX-2655 (2Q 2008 Quarterly Compliance Report) (PPLP004401342) at -361 (65 resolved with 7 days, and 2 outstanding after 90 days); JX-2657 (4Q 2008 Quarterly Compliance Report) (PPLP004402205) at -225 (78 resolved with 7 days, and all within 90 days); JX-2658 (1Q 2009 Quarterly Compliance Report) (PPLP004402651) at -671 (77 resolved with 7 days, and 1 outstanding after 90 days); JX-2659 (2Q 2009 Quarterly Compliance Report) (PPLPC012000236639) at 19 (108 resolved with 7 days, and 1 outstanding after 90 days); JX-2660 (3Q 2009 Quarterly Compliance Report) (PPLP004402982) at -999 (86 resolved with 7 days, and 2 outstanding after 90 days); JX-2661 (4Q 2009 Quarterly Compliance Report) (PPLP004403707) at -721 (88 resolved with 7 days, and all within 90 days); JX-2662 (1Q 2010 Quarterly Compliance Report) (PPLP004404102) at -115 (70 resolved with 7 days, and all within 90 days); JX-2665 (4Q 2010 Quarterly Compliance Report) (PPLP004405709) at -719 (152 resolved within 7 days, 2 outstanding after 90 days); JX-2674 (1Q 2013 Quarterly Compliance

204. Very few of those inquiries pertained to abuse or diversion, as demonstrated by two charts provided to the Board in 2017 summarizing the "Top 5 Direct Inquiry Types" and "Top 5 Hotline Types" for 2014, 2015 and 2016—and which include no ADD issues in the 5 most common direct inquiries and just 4 hotline inquiries about ADD issues in 2015 and 3 in 2016:[293]



205. Management explained to the Board the methods used to achieve Purdue's adherence to its anti-diversion programs.

206. Based on materials and presentations from management, PPI Directors had every reason to understand that Purdue was successfully fighting abuse and diversion and satisfying ADD Program obligations.

207. By way of example:

Report) (PPLP004409694) at -696 ("Monthly call note reviews now being completed on a 30 day cycle"); JX-1834 (Mar. 2017 Quarterly Compliance Report) (PPLP004413913) at -922 (average days to investigate hotline calls was 11 in 2014, 7 in 2015 and 8 in 2016, and average days to investigate direct inquiries was 48 in 2014, 42 in 2015 and 49 in 2016); JX-2684 (Jun. 2017 Quarterly Compliance Report) (PPLP004414244) at -254 (39 resolved within 7 days, 3 outstanding after 60 days).

[293] JX-1834 (Mar. 2017 Quarterly Compliance Report) (PPLP004413913) at -922.

- After the ADD Program was incorporated into the requirements of the 27 State Consent Judgments that Purdue entered into in 2007, Purdue's management continually advised the Board over the next five years that Purdue was in full compliance with the Consent Judgments.[294]

- The Board was repeatedly informed that "[a]ll sales employees (and select other employees) were trained on Purdue's Abuse and Diversion Detection (ADD) Program"[295] and that annual ADD training remained "current"[296] and was "continu[ing]."[297]

- The Board received updates about the "extensive live training sessions," online training, field training and workshops provided to sales and marketing staff on topics including "Complete and Effective Call Notes," as required by the ADD Program.[298]

- Management reported that monitoring of sales representatives' call notes was a primary source of ADD Program monitoring and reporting.[299]

- The Board was informed that District Managers reviewed call notes on a weekly

[294] JX-1827 (Aug. 6, 2007 Quarterly Compliance Report) (PPLP004399954) at -955 ("Purdue is in full compliance with AG Agreement."). *See also* JX-1828 (Feb. 8, 2008 Quarterly Compliance Report) (PPLPC019000195607) at slide 3 ("Purdue in compliance with AG Agreements / Abuse & Diversion Detection (ADD) training current"); JX-2655 (2Q 2008 Quarterly Compliance Report) (PPLP004401342) at -344 ("Purdue is also in full compliance with its AG Agreements"); JX-2660 (3Q 2009 Quarterly Compliance Report) (PPLP004402982) at -986 ("Purdue is also in full compliance with its AG Agreements"); JX-1909 (Feb. 24, 2010 Board Proposal) (PURDUE-COR-00028015) at p. 3 ("Satisfied CIA and AG requirement for all … Abuse and Diversion Detection Reports"); JX-1913 (January 18, 2012 Board Compensation Committee Presentation) (PPLPC042000025057) at slide 28 ("Satisfied CIA and AG requirement for all … Abuse and Diversion Detection Reports").

[295] JX-2046 (July 15, 2007 Quarterly Report to the Board) (PPLP004366645) at -697.

[296] JX-1828 (Feb. 8, 2008 Quarterly Compliance Report) (PPLPC019000195607) at slide 3; JX-2655 (2Q 2008 Quarterly Compliance Report) (PPLP004401342) at -344; JX-2660 (3Q 2009 Quarterly Compliance Report) (PPLP004402982) at 986.

[297] JX-1830 (2Q 2012 Quarterly Compliance Report) (PPLPUCC9002892662) at slide 6.

[298] JX-2664 (3Q 2010 Quarterly Compliance Report) (PPLP004405460) at -470–74; JX-2046 (July 15, 2007 Quarterly Report to the Board) (PPLP004366645) at -697.

[299] Under 6/15/2007 SOP 1.7.1, a primary procedure for a sales representative to file an ADD Report was to enter a call note into the Phoenix system. JX-1871 (6/15/07 ADD SOP 1.7.1) (PPLP003429997) at -999.

basis,[300] and that the Compliance Department conducted monthly word-search reviews of call notes.[301]

- In 2011 and 2014, for example, the Board was informed of particular management audits of the call note program.[302] Management advised that its review process included "analyz[ing] all call notes for 30 key words, such as: dosing, formula, benefit, abuse, safer, [and] milder," with over 125,000 call note hits generated each month and approximately 25% of those notes reviewed in 2011.[303]

- The Board was informed that, by 2012, the review process had been transferred to the Compliance Department to allow "review and resolution of issues in real time"[304] and refined to include the "review of a random selection of call notes" so that "we will be looking at call notes for every representative each month."[305]

- The Chief Compliance Officer told the Board in 2012 that "the Board's takeaway from this new process should be that Purdue is doing an even better more thorough job of monitoring field activity through these improvements."[306]

- Management frequently advised the Board of the results of Field Contact Report audits, and they reflected the efficacy of Purdue's ADD Program.[307]

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[300] JX-2656 (3Q 2008 Quarterly Compliance Report) (PPLP004402032) at -086.

[301] JX-2657 (4Q 2008 Quarterly Compliance Report) (PPLP004402205) at -207.

[302] JX-2666 (1Q 2011 Quarterly Compliance Report) (PPLP004406032) at -046 ("2011 Planned Audit List," including "Call Note Audits"); JX-2667 (2Q 2011 Quarterly Compliance Report) (PPLP004406466) at -472 ("Call note review, auditing"); JX-2677 (1Q 2014 Quarterly Compliance Report) (PPLP004411166) at -172 ("Call Note Follow-Up Audit … No Critical Findings … improvements shown from previous audit").

[303] JX-2667 (2Q 2011 Quarterly Compliance Report) (PPLP004406466) at -484.

[304] JX-2672 (3Q 2012 Quarterly Compliance Report) (PPLP004408439) at -443.

[305] JX-2670 (1Q 2012 Quarterly Compliance Report) (PPLP004407950) at -953.

[306] JX-2670 (1Q 2012 Quarterly Compliance Report) (PPLP004407950) at -953. *See also* JX-2674 (1Q 2013 Quarterly Compliance Report) (PPLP004409694) at -696 ("Reviewing 10% of approx. 90K call notes generated monthly / Faster spotting of issues"); JX-2675 (3Q 2013 Quarterly Compliance Report) (PPLP004410506) at -510 (11.82% of call notes reviewed)

[307] *See, e.g.*, JX-2657 (4Q 2008 Quarterly Compliance Report) (PPLP004402205) at -215–16; JX-2658 (1Q 2009 Quarterly Compliance Report) (PPLP004402651) at -663–64; JX-2661 (4Q 2009 Quarterly Compliance Report) (PPLP004403707) at -712; JX-2662 (1Q 2010 Quarterly Compliance Report) (PPLP004404102) at -106; JX-2663 (2Q 2010 Quarterly Compliance Report) (PPLP004404551) at -554; JX-2664 (3Q 2010 Quarterly Compliance Report) (PPLP004405460) at -492; JX-2665 (4Q 2010 Quarterly Compliance Report) (PPLP004405709) at -713; JX-2666

- In 2016, for example, the Board was advised that two audits of Field Contact Reports had been completed to assess whether District Managers were accurately documenting compliance issues and appropriately evaluating sales reps. These audits resulted in no critical findings.[308]

- Management reported that, at Purdue's national sales meetings, management reviewed with sales representatives ADD Report requirements,[309] gave them "Key reminders" about ADD reporting,[310] and presented scenario-based workshops on ADD Reporting.[311]

- Management provided regular confirmations that Purdue was meeting its ADD obligations[312] and management committed, after the end of the CIA, "to continue OxyContin Abuse and Diversion Detection Program predicated on [SOP] 1.7.1."[313]

- The Board's Compensation Committee—on which Richard Sackler served—received consistent reports reflecting Purdue's fulfillment of its ADD Program requirements and related efforts because they were factored into employees' compensation.[314] In 2013, this included a report from management that "Purdue

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(1Q 2011 Quarterly Compliance Report) (PPLP004406032) at -036; JX-2667 (2Q 2011 Quarterly Compliance Report) (PPLP004406466) at -469; JX-2675 (3Q 2013 Quarterly Compliance Report) (PPLP004410506) at -512; *see also* JX-1881 (2013 Sales Force SOP) (PPLP003430093) at -131; JX-1884 (2016 Sales Force SOP Manual) (PPLP003578668) at -717; JX-2291 (IRO's Report on Additional Promotional and Product Services Systems Assessment: Funding of Charitable Grants and Sponsorships, Reporting Period 3) (PPLP004434741) at -750–51.

[308] JX-2677 (1Q 2014 Quarterly Compliance Report) (PPLP004411166) at -173.

[309] JX-2657 (4Q 2008 Quarterly Compliance Report) (PPLP004402205) at -226.

[310] JX-1828 (Feb. 8, 2008 Quarterly Compliance Report) (PPLPC019000195607) at slide 20.

[311] JX-2661 (4Q 2009 Quarterly Compliance Report) (PPLP004403707) at -715.

[312] JX-2243 (October 31, 2007 Budget Presentation to the Board) (PPLP004400043) at -382 ("All specific requirements" for the ADD program were "timely met.").

[313] JX-1830 (2Q 2012 Quarterly Compliance Report) (PPLPUCC9002892662) at slide 10. *See also, e.g.*, JX-1834 (Mar. 2017 Quarterly Compliance Report) (PPLP004413913) at -919; JX-2684 (Jun. 2017 Quarterly Compliance Report) (PPLP004414244) at -248.

[314] *See* JX-2265 (2/11/09 Compliance Memo) (PPLPC051000068931) at -931 ("very much heightened sensitivity to AE, ROC, product quality and ADD reporting"); JX-1908 (1/18/10 Scorecard Summary) (PPLPC057000007180) at -192 ("the FDA and DEA inspections this year were excellent, without any adverse findings ...."); JX-1910 (1/21/11 Presentation to Compensation Committee) (PPLPUCC9003754547) at slide 12 ("All requirements satisfied" for "Hotline" and "Abuse and Diversion Detection Reports;" "FDA inspections and DEA audits resulted in no citations, findings or 483's"); JX-1913 (1/18/12 Presentation to Compensation Committee) (PPLPC042000025057) at slide 28 ("Attained all objectives related to" "Hotline" and

[was] recognized by DEA, FDA, etc. for responsible actions and saving lives."[315]

- Management advised the Board in 2010 the General Counsel's office had begun consulting with the Order Monitoring System Committee to assist with "policy development and implementation" for "new DEA requirements regarding response to "suspicious orders."[316]

C. Regulators and Auditors Ratified Purdue's Implementation of Its ADD Program

1. The Board Knew That 27 AGs Monitored Purdue's ADD Program for 3 Years and Required That Purdue Maintain It for a Decade

208. The 27 Consent Judgments that Purdue entered into in 2007 endorsed—and required that Purdue maintain for a decade—its ADD Program.

209. The Consent Judgments mandated that Purdue "establish, implement and follow an OxyContin abuse and diversion detection program"[317]—essentially the same program that Purdue had introduced in 2002, newly christened the Abuse and Diversion Detection Program.[318]

210. The specific indicia of potential abuse and diversion that the AGs incorporated

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"Abuse and Diversion Reports;" "Adherence to Sales SOPs," "Timely reporting of Adverse Events, Reports of Concern, Product Complaints, and Abuse and Diversion Detection Reports"); JX-2383 (11/21/13 Presentation to Compensation Committee) (PPLPC045000016839) at slide -849 ("fully meeting all reporting requirements … Adherence to Sales SOPs").

[315] JX-2328 (1/18/12 President's Review of Significant Accomplishments and Disappointments in 2011) (PPLPC042000025039).

[316] JX-2071 (11/23/10 Board Slides) (PWG004349878) at -936. *See also* DEA Suspicious Orders Report System, https://www.deadiversion.usdoj.gov/sors/index.html .

[317] *See* JX-1900 (Ky. Consent Judgment) at ¶13.

[318] *See* JX-1863 (10/15/02 ADD SOP) (PDD1503450011); JX-1864 (11/1/02 ADD SOP 1.7.1) (PPLP003430434). The ADD Program was launched on October 15, 2002, approximately 16 months after June 30, 2001, which marked the end of the period in which Purdue had engaged in the misconduct to which it pled guilty in 2007. *See United States v. Purdue Frederick Co., Inc.*, Case 1:07-cr-00029-JPJ (W.D. Va. May 10, 2007), ECF No. 5 (Information) at ¶¶6, 20, 27, 37, 38, 43; *United States v. Purdue Frederick Co., Inc.*, Case 1:07-cr-00029-JPJ (W.D. Va. May 10, 2007), ECF No. 5, Count One ¶2 and Ex. B (2007 Agreed Statement of Facts) at ¶¶20, 27, 37, 38, 43–45.

into the Consent Judgments for the ADD Program were taken nearly verbatim from Purdue's existing ADD Program.[319]

211. Consistent with Purdue's preexisting policies, the Consent Judgments required Purdue to investigate each ADD Report and to take "further steps as may be appropriate based on the facts and circumstances"—such as providing further education to the prescriber, stopping all marketing to the prescriber, or reporting the prescriber to the "appropriate medical, regulatory or law enforcement authorities."[320]

212. The Board was also informed that Purdue's updated SOP for the ADD Program in June 2007 was sent to the 27 Consent Judgment AGs, together with Purdue's certification that the ADD Program had been established and implemented, to demonstrate its compliance with the Consent Judgments' requirements.[321]

213. None of the receiving AGs responded with any criticism or objection.

214. From 2008-10, the Board was aware of and reasonably relied on Purdue's annual certifications to the consent judgment AGs confirming Purdue's compliance with the ADD Program.[322]

[319] *Compare* Ky. Consent Judgment at ¶13 *with* JX-1864 (11/1/02 ADD SOP) (PPLP003430434) and JX-1867 (10/6/03 ADD SOP 1.7.1) (PDD1503493410).

[320] *See, e.g.,* Ky. Consent Judgment at ¶13. All 27 Consent Judgments contained identical substantive terms.

[321] *See* JX-2238 (6/20/07 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance) (PPLPC026000033097); JX-1827 (Aug. 6, 2007 Compliance Report) (PPLP004399954) at -956 [redacted]

[322] *See* JX-2257 (5/7/08 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance) (PPLPC026000041921). *See also* JX-2266 (5/7/09 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance) (PWG004407107); JX-2284 (5/7/10 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance) (PPLPC026000064681). *See also* Ky. Consent Judgment at ¶24(e).

215. Each year, Purdue furnished to the Consent Judgment States "a report containing basic statistics on Purdue's Abuse and Diversion Detection program, including … statistics on the number of reports, the number of investigations, and a summary of the results, including the number of 'Do Not Call' determinations."[323]

216. As mandated by the Consent Judgments, the information provided did "not include the names of any specific Health Care Professionals,"[324] But that information was available to all Consent Judgment States on request, and it was in fact supplied to requesting AGs when they requested it.[325]

217. The Consent Judgments required that Purdue maintain the ADD Program for ten years, from 2007-2017.[326]

2. NYAG Ratified the ADD Program in 2015 and That NYAG's Auditor Endorsed Purdue's Implementation of It From 2015-2018

218. The New York Attorney General ratified Purdue's ADD Program again in 2015 by requiring that Purdue maintain it as long as Purdue marketed opioids—and an independent auditor approved by NYAG confirmed the reasonableness, conscientiousness and good faith of Purdue's ADD Program decision-making in a series of annual reviews from 2015-2018.

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[323] Ky. Consent Judgment at ¶24(e). *See* JX-2257 (5/7/08 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance) (PPLPC026000041921). *See also* JX-2266 (5/7/09 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance) (PWG004407107); JX-2284 (5/7/10 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance) (PPLPC026000064681).

[324] Ky. Consent Judgment at ¶24(e). Pursuant to Consent Judgment ¶24(f), "upon written requests, the [AGs] may obtain state-specific information as described in subsection (e)."

[325] *See*, *e.g.*, JX-2267 (5/18/09 Purdue Letter to Virginia AG) (PPLPC051000075710); JX-2373 (October 10, 2013 Purdue Letter to Tennessee AG) (PPLPC049000079234).

[326] *See* Ky. Consent Judgment at ¶13.

219. In 2014, the New York Attorney General launched an investigation into "Purdue's Abuse and Diversion Detection ('ADD') Program (also known as the 'Region Zero' program)."[327]

220. This investigation concluded in August 2015 with the entry of an Assurance of Discontinuance.

221. The AOD was entered into on a neither-admit-nor-deny basis with Purdue paying only $75,000, in "penalties, fees and/or costs."[328]

222. In the AOD, the New York Attorney General found that Purdue's "<u>ADD Program can be an effective tool in identifying potential abuse and illegal diversion of opioids</u>," and determined that there were some "opportunities for improvement."[329]

223. The AOD required that Purdue maintain the ADD Program "for as long as Purdue promotes OxyContin to [prescribers] through sales representatives."[330]

224. The AOD included modest modifications to the program, including the addition of two criteria—to the preexisting 13—that would trigger an ADD Report.[331] The AOD also required that Purdue review media stories and data sources "to identify [prescribers] who should [be] reviewed for potential placement on the No-Call [Region Zero] List"[332] and "provide to the [New York Attorney General] the names of any [prescribers] in New York whom it has placed

[327] AOD at ¶8.

[328] AOD at ¶38.

[329] *Id.* at ¶15.

[330] *Id.* at ¶28.

[331] *Id.* at ¶29.

[332] *Id.* at ¶31(d).

on the No-Call List" on a monthly basis.[333]

225. The AOD also required that Purdue hire an independent, outside auditor approved by the New York Attorney General, for a period of three years, to monitor and report on (i) Purdue's compliance with its ADD Program requirements and (ii) "the reasonableness of Purdue's decisions regarding whether to continue marketing or promoting opioid products to the [prescribers] at issue in each ADD Report."[334]

226. With the New York Attorney General's approval, Purdue hired as its auditor Douglas R. Jensen, Esq., a former Chief of the Narcotics Unit in the United States Attorney's Office for the Southern District of New York. [335]

227. Beginning in 2016, the Auditor reviewed all "continue to call" or "resume calling" determinations Purdue's Law Department made concerning HCPs that were the subject of ADD Reports, and he produced three annual reports outlining his findings.[336]

228. The Auditor's three reports confirmed that Purdue was implementing its ADD Program "reasonabl[y]," "conscientiously and in good faith," and that Purdue was in compliance with the AOD.[337]

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[333] *Id.* at ¶31(c).

[334] *Id.* at ¶41(b).

[335] *Douglas R. Jensen*, WHITE & CASE, https://www.whitecase.com/people/douglas-jensen.

[336] *See* JX-2699 (10/7/16 Auditor's First Report on Purdue's ADD Program) (PPLP004473667) at -674, -693; JX-2700 (10/20/17 Auditor's Second Report on Purdue's ADD Program) (PPLP004473709) at -715–16; JX-2701 (10/19/18 Auditor's Third Report on Purdue's ADD Program) (PPLP004473738) at -743.

[337] JX-2699 (10/7/16 Auditor's First Report on Purdue's ADD Program) (PPLP004473667) at -668. *See* JX-2700 (10/20/17 Auditor's Second Report on Purdue's ADD Program) (PPLP004473709) at -710 ("the Company continues to operate the ADD Program in compliance with [the AOD]"); JX-2701 (10/19/18 Auditor's Third Report on Purdue's ADD Program)

229. Over the course of three years, the Auditor identified just one determination—out of a total of 906[338]—that he thought was not reasonable. Even as to this one, the Auditor found that Purdue had acted "conscientiously" and in "good faith,"[339] and observed that, "based upon prior experience the Auditor believes it likely the Company would have reconsidered its position" in light of the Auditor's finding but, because the Company had "stopped promoting opioids to prescribers altogether on February 12, 2018, such discussions did not take place."[340]

230. In 2016, the New York Attorney General entered into an Assurance of Discontinuance with another manufacturer of oxycodone products and required it to adopt an ADD Program nearly identical to Purdue's.[341]

3. **The Board Was Aware That Other Governmental Agencies Reviewed Purdue's ADD Program and Provided No Negative Feedback**

231. The Board was informed that several governmental agencies reviewed Purdue's ADD Program—and the Company's implementation of it—and none criticized or commented

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(PPLP004473738) at -740 ("the Company continued to operate the ADD Program in compliance with [the AOD]").

338 Ninety-eight determinations in 2016, 261 in 2017, and 547 in 2018. JX-2699 (10/7/16 Auditor's First Report on Purdue's ADD Program) (PPLP004473667) at -668; JX-2700 (10/20/17 Auditor's Second Report on Purdue's ADD Program) (PPLP004473709) at -711; JX-2701 (10/19/18 Auditor's Third Report on Purdue's ADD Program) (PPLP004473738) at -742.

339 JX-2701 (10/19/18 Auditor's Third Report on Purdue's ADD Program) (PPLP004473738) at -741.

340 JX-2701 (10/19/18 Auditor's Third Report on Purdue's ADD Program) (PPLP004473738) at -749. In March 2017, Purdue had hired outside counsel, Spears Manning, to assist Purdue with all ADD determinations. Spears Manning was responsible for analyzing information collected as to each reported prescriber, interviewing relevant sales representatives, and drafting an initial recommendation as to whether Purdue should continue calling the prescriber. *See* JX-2700 (10/20/17 Auditor's Second Report on Purdue's ADD Program) (PPLP004473709) at -717.

341 In the Matter of Endo Solutions Inc. and Endo Pharm. Inc., Assurance No. 15-228 (Mar. 1, 2016)¸*available at* https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

negatively on it.[342]

- **The Government Accountability Office ("GAO").** In 2003, Purdue shared with GAO the number of ADD investigations the Company had conducted (483), the number of prescribers it had placed in Region Zero (197), and the number of those prescribers whom Purdue had referred to legal, medical, or regulatory authorities (39).[343] Later that year, the GAO issued a report to Congress entitled PRESCRIPTION DRUGS: OXYCONTIN ABUSE AND DIVERSION AND EFFORTS TO ADDRESS THE PROBLEM.[344] This 2003 GAO report recognized that "Purdue has initiated drug abuse and diversion education programs, taken disciplinary actions against sales representatives who improperly promote OxyContin, and referred physicians who were suspected of improperly prescribing OxyContin to the appropriate authorities" and that, "[a]s of September 2003, Purdue—through its own investigations—had identified 39 physicians and other health care professionals who were referred to legal, medical, or regulatory authorities for further action. Most of the 39 referrals stemmed from reports by Purdue's sales force."[345] The 2003 GAO report recommended that the FDA encourage other pharmaceutical manufacturers to develop "a strategy for monitoring the use of these drugs and identifying potential abuse and diversion problems."[346] In 2011, Purdue again provided information about its ADD Program to the GAO, and the 2011 GAO report that followed included no negative comments about it.[347]

- **OIG of HHS.** The 2007 CIA required the IRO to issue, for the OIG's review, reports detailing how Purdue monitored its sales representatives for compliance with Purdue's Promotion Monitoring Program ("**PMP**"). The PMP was the process through which District Managers monitored sales representatives' interactions with HCPs and compliance with Purdue policies, including the ADD Program.[348] As

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[342] *See* JX-2437 (6/10/16 Email to Board) (PPLPC011000106533).

[343] JX-2222 (Sept. 22, 2003 email from Ted Hester to Opal Winebrenner, *et al*., with attachment) (BATES No. 9101439815).

[344] JX-2181 (U.S. Gen. Accounting Office, GAO-04-110, PRESCRIPTION DRUGS: OXYCONTIN ABUSE AND DIVERSION AND EFFORTS TO ADDRESS THE PROBLEM (2003), *available at* https://www.gao.gov/assets/gao-04-110.pdf).

[345] *Id*. at 34, 41.

[346] *Id*. at 42.

[347] *See* JX-2185 (U.S. Gen. Accounting Office, GAO-12-115, PRESCRIPTION PAIN RELIEVER ABUSE; AGENCIES HAVE BEGUN COORDINATING EDUCATION EFFORTS, BUT NEED TO ASSESS EFFECTIVENESS 38-39 (2011), *available at* https://www.gao.gov/assets/gao-12-115.pdf).

[348] CIA at §III(D)(1)(b) & Appendix B §II(A)(7); JX-2272 (7/30/09 IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 2) (PPLP004433812) at -815, -990–91; JX-2315 (9/23/11 IRO's Report on Promotional and Product Services Systems Engagement,

the IRO reported to the OIG in 2009 and 2011, the PMP required District Managers to monitor sales representatives for (1) their knowledge of indicators of possible diversion by healthcare professionals, and (2) filing reports as required under the ADD Program.[349] The IRO's reports discussed in detail Purdue's implementation of the PMP, including how sales reps were monitored for compliance. After reviewing these reports and receiving other requested information, the OIG certified Purdue's compliance with the CIA.[350]

- **DEA.** Purdue met with the DEA multiple times to discuss its anti-diversion efforts. On December 9, 2011, and October 16, 2013, Purdue gave presentations to the DEA concerning the reduction in abuse and diversion resulting from introduction of ADF OxyContin.[351] Purdue met with the DEA at least twice in 2011 to discuss the ADD Program.[352] In April and October of 2011, Purdue discussed with the DEA the ADF of OxyContin (also called "**ORF**" (OxyContin Reformulated)) and received feedback from DEA that "*ORF has made a tremendous difference*," "*No longer hearing about OxyContin from field offices," and "ORF is saving lives.*"[353] At the April 2011 meeting, Purdue discussed "ADD (and SOP 1.7.1) in general"—which the "DEA participants were very interested in learning more about"—and described "our efforts in depth, including training and expectation of the field reps."[354]

- In addition, in 2010 the Board was informed that DEA closed a "product diversion investigation which had been opened since early 2010,"[355] and in 2009 the Board

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Reporting Period 4) (PPLPC021000573227); JX-2314 (9/23/11 IRO's Promotional and Product Services Transactions Engagement, Reporting Period 4) (PPLP004432560).

[349] JX-2272 (July 30, 2009 IRO's Report on Promotional and Product Services Systems Engagement Reporting Period 2) (PPLP004433812) at -833–839; JX-2315 (Sept. 23, 2011 Promotional and Product Services and Services Systems Engagement) (PPLPC021000573227 at -245–250).

[350] JX-2691 (Second OIG Certification) (PPLP004250164); JX-1839 (Fourth OIG Certification) (PPLP004428603).

[351] *See* JX-2325 (12/9/11 presentation entitled "Epidemiology studies of Reformulated OxyContin's effect on opioid abuse") (PPLPC019000618954); JX-2375 (10/16/13 presentation entitled "Update on Findings Regarding Reformulated OxyContin") (PPLPC020000725747).

[352] *See* JX-2431 (PPLP ADD Program Background) (PPLPC031001431032).

[353] JX-2323 (2012 Budget Presentation to Board) (PPLPUCC9011086649) at slide 6.

[354] *See* JX-2302 (4/12/11 email from Jack Crowley describing meeting with DEA) (PPLPC053000051168) at -170. A Purdue email recapping that meeting reported that the DEA told Purdue that its abuse and diversion detection efforts were "ahead of the curve—way ahead of any other manufacturer—light years ahead." *Id.*

[355] JX-2058 (3Q 2010 Board Report) (PPLP004366991) at -998.

learned that DEA inspected Purdue's Wilson and Coventry manufacturing sites and found no deficiencies.[356]

- **NIDA, NDCP, and CDC.** In 2012, Purdue also met with the National Institute of Drug Abuse, the Office of National Drug Control Policy, and CDC to discuss the ADD Program.[357]

232. The Board reasonably relied on the fact that State and federal regulators reviewed Purdue's ADD Program without negative feedback for well over a decade as one factor in coming to the understanding that Purdue's anti-diversion activities were reasonable and sufficient.

4. Purdue Shared ADD/Region Zero Information with Regulators

233. Between 2002 and 2018, Purdue referred at least 222 Region Zero prescribers to the DEA, including 82 in April 2011 alone.[358]

234. Between 2013 and 2015, Purdue supplied the names of 774 Region Zero prescribers to 25 regulators in 17 states, as follows:

STATE OR STATE AGENCY	DATE	# OF HCPS DISCLOSED	SOURCE
1. Alabama State Board of Medical Examiners	March 11, 2014	23	JX-2400 (PPLP004437472)
2. Arizona Board of Osteopathic Examiners in Medicine and Surgery	2/28/14	11	JX-2396 (PPLP004437482)
3. California Board of Podiatric Medicine	9/26/13	1	JX-2371 (PPLPUCC9011507904)
4. California Board of Registered Nursing	9/25/13	3	JX-2367 (PPLP004437542)

[356] *See* JX-2069 (Jan. 21, 2010 Board Agenda) (PPLPC044000023970) at -4004.

[357] *See* JX-2431 (PPLP ADD Program Background) (PPLPC031001431032).

[358] *See* JX-2302 (4/12/11 email from Jack Crowley describing meeting with DEA) (PPLPC053000051168) at -170. Jack Crowley, Purdue's Executive Director of Controlled Substance Act Compliance and a 28-year veteran of the DEA, also "routinely" made informal referrals to the DEA. *See* JX-2002 (1/10/19 Jack Crowley MDL Dep. Tr.) at 42:8–10, 287:23–25.

State or State Agency	Date	# of HCPs Disclosed	Source
5. California Dental Board	9/12/13	1	JX-2362 (PPLPC051000189775)
6. California Medical Board	9/11/13	49	JX-2360 (PPLPC049000079268)
	9/25/13	113	JX-2369 (PPLPC051000189745)
7. California Osteopathic Medical Board	9/25/13	13	JX-2368 (PPLPC051000189739)
8. California Physician Assistant Board	9/26/13	9	JX-2370 (PPLPUCC9011507902)
9. Georgia Composite Medical Board	2/27/14	66	JX-2393 (PPLP004437620)
10. Illinois Department of Financial and Professional Regulation	2/12/14	34	JX-2389 (PPLP004437654)
11. Kansas State Board of Healing Hearts	3/4/14	9	JX-2398 (PPLP004437673)
12. Nevada State Board of Medical Examiners	8/27/13	35	JX-2356 (PPLPC049000076533)
	8/11/15	7	JX-2424 (PPLPUCC9011512808)
	5/17/16	6	JX-2434 (PPLPUCC9011562267)
13. Nevada State Board of Osteopathic Medicine	9/26/13	6	JX-2372 (PPLPUCC9011507906)

STATE OR STATE AGENCY	DATE	# OF HCPS DISCLOSED	SOURCE
14. Nevada State Board of Pharmacy	9/3/13	1	JX-2358 (PPLPC049000079271)
15. New Jersey Office of Attorney General	11/8/13	45	JX-2379 (PPLP004437814)
16. North Dakota State Board of Medical Examiners	3/7/14	2	JX-2399 (PPLP004437795)
17. Oregon Medical Board	5/20/14	19	JX-2410 (PPLPUCC9011455002)
18. Pennsylvania Department of State, Bureau of Professional/Occupational Affairs	2/28/14	98	JX-2397 (PPLP004437994)
19. Rhode Island Board of Medical Licensure & Discipline	3/11/14	16	JX-2401 (PPLP004438019)
20. Tennessee Office of Attorney General	10/15/13	75	JX-2374 (PPLP004438085)
21. Virginia Department of Health Professions	2/19/14	64	JX-2390 (PPLP004438105)
22. West Virginia Board of Medicine	2/27/14	25	JX-2394 (PPLP004438134)
23. West Virginia Board of Osteopathic Medicine	2/27/14	7	JX-2395 (PPLP004438138)
24. Wisconsin Department of Safety & Professional Services	2/25/14	33	JX-2391 (PPLP004438118)
	4/4/14	N/A	JX-2405 (PPLPUCC9011483548)
	4/28/14	N/A	JX-2406 (PPLP004438113)
25. Wyoming Board of Medicine	2/26/14	3	JX-2392 (PPLP004438157)
<u>TOTAL</u>		**<u>774</u>**	

235. In 2013, Purdue furnished the names of Region Zero HCPs in Pennsylvania,

New Jersey, and Delaware to the U.S. Attorney for the Eastern District of Pennsylvania.[359] In 2014, Purdue twice provided Region Zero information to the U.S. Senate Caucus on International Narcotics Control.[360]

236. Purdue's 2007-2010 reports to the 27 Consent Judgment Attorneys General included the number of ADD investigations conducted, the number of HCPs or pharmacies placed in Region Zero and reported to law enforcement, and how many of those HCPs were high, mid, and low-level OxyContin prescribers, or who did not prescribe OxyContin at all, as follows:[361]

- In May 2008, Purdue reported that, between May 7, 2007 and May 2, 2008, its Law

[359] JX-2363 (9/13/13 Letter to Eastern District of Pennsylvania AUSA) (PPLPC049000079240).

[360] JX-2388 (1/7/14 Letter to Senators) (PPLPC049000103061); JX-2403 (3/12/14 Letter to Senators) (PPLPC049000103152).

[361] *See* JX-2257 (5/7/08 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance) (PPLPC026000041921); JX-2266 (5/7/09 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance) (PWG004407107); JX-2284 (5/7/10 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance) (PPLPC026000064681). The following is a summary of these reports:

		5/08 Certification	5/09 Certification	5/10 Certification	Total
HCPs Investigated		**226**	**239**	**480**	**945**
	High	*42*	*88*	*140*	*270*
	Medium	*39*	*49*	*102*	*190*
	Low	*143*	*81*	*157*	*381*
	No Oxy	*not reported*	*21*	*81*	*102*
Region 0 Placements		**116**	**225**	**300**	**641**
Referral to authorities		4	7	11	22

Department conducted 226 investigations; that in 116 of the cases, Purdue decided that the sales reps should not call on the HCP; that in four of those cases, Purdue initiated a referral to legal, medical or regulatory authorities; and that, in many of the remaining cases, "Purdue was already aware that an investigation was pending" and "actively cooperated with the investigation by furnishing documents, answering questions, or providing potential witnesses."[362]

- In May 2009, Purdue reported that, in the prior year, its Law Department conducted 239 investigations; stopped marketing to the HCPs in 225 of those cases; referred seven to the authorities; and was aware, in many of the other cases, that the HCPs were the subject of a pending investigation, with which Purdue actively cooperated.[363]

- In May 2010, Purdue reported that, in the prior year, its Law Department conducted 480 investigations; stopped marketing to the HCPs in 300 of those cases; referred 11 HCPs to the authorities; and was aware that, in many of the other cases, the prescribers were the subject of a pending investigation with which Purdue actively cooperated.[364]

5. **The Board Understood That Diversion, Abuse, and Prescriptions Written By Region Zero HCPs Fell Substantially After ADF OxyContin Was Introduced In 2010**

237. In August 2010, Purdue launched reformulated OxyContin, the first abuse-deterrent opioid product ever approved by the FDA.[365]

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[362] JX-2257 (5/7/08 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance) (PPLPC026000041921) at -928.

[363] JX-2266 (5/7/09 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance) (PWG004407107) at -113.

[364] JX-2284 (5/7/10 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance) (PPLPC026000064681) at -688. Although the Consent Judgments barred Purdue from including in these reports "the names of any specific Health Care Professionals" (Ky. Consent Judgment ¶24(e)), States had the right to request Region Zero information from Purdue at any time (*see id*. at ¶24(f) ("upon written requests, the [AGs] may obtain state-specific information as described in subsection (e)")), and Purdue provided information to the states whenever requested. *See, e.g.,* JX-2267 (5/18/09 Letter from Purdue Counsel to Virginia Attorney General's Office) (PPLPC051000075710) (providing a list of Virginia healthcare professionals on Purdue's "Do Not Call" list).

[365] *See* Jeremy A. Adler & Theresa Mallick-Searle, *An Overview of Abuse-Deterrent Opioids and Recommendations for Practical Patient Care*, 2018 J. MULTIDISCIPLINARY HEALTHCARE 323, 327

238. While the reformulated tablet is not abuse-proof (multiple pills can be ingested orally despite the label's warnings), it is—as the FDA has determined—abuse-deterrent because it is difficult to crush and, when crushed, does not dissolve into a powder that is capable of being inhaled or snorted.[366]

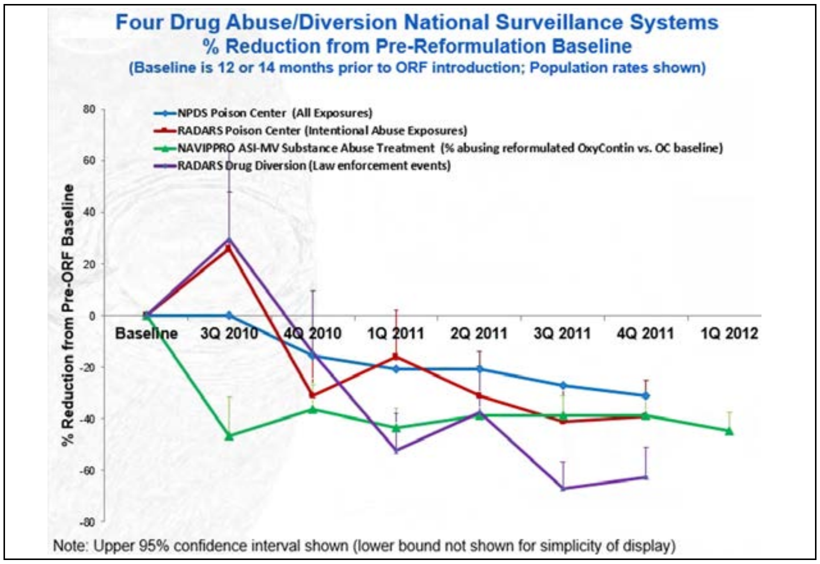
239. Based on extensive data presented by management following the introduction of the abuse-deterrent formulation in 2010, the Board understood that the new formulation produced a substantial reduction in (1) diversion, (2) abuse and (3) the number of prescriptions written by prescribers the Company had placed in Region Zero.

a. Reduction of Diversion

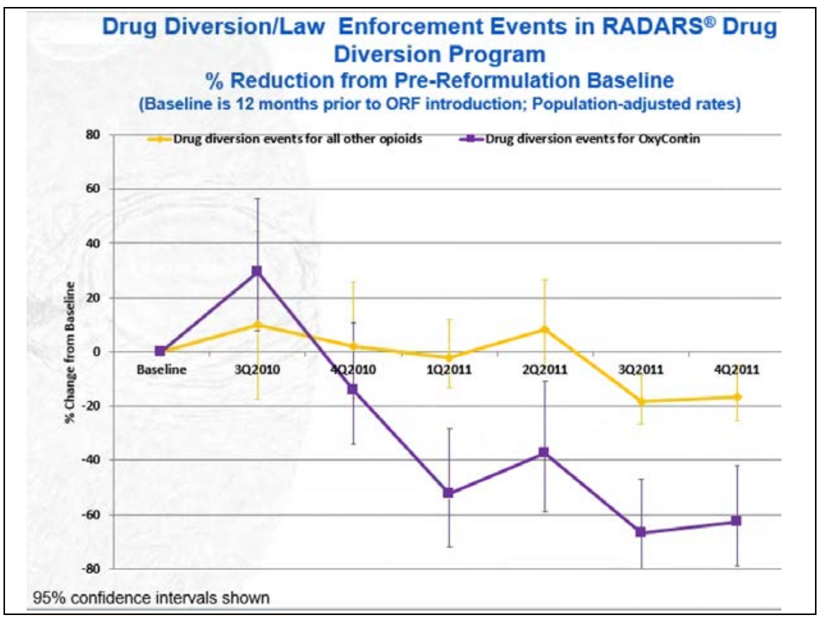
240. Purdue's management provided the Board with statistics, drawn from third-party data, showing that diversion fell substantially following the introduction of the abuse-deterrent formulation. This is shown, for example, on the following two slides that management presented to the Board at the June 18, 2012 Board Meeting:

(2018), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6045950/pdf/jmdh-11-323.pdf.

[366] *See* FDA Press Release, *FDA approves abuse-deterrent labeling for reformulated OxyContin* (April 16, 2013): "The FDA has determined that the reformulated product has abuse deterrent properties. The tablet is more difficult to crush, break, or dissolve. It also forms a viscous hydrogel and cannot be easily prepared for injection." https://web.archive.org/web/20130419012709/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm348252.htm

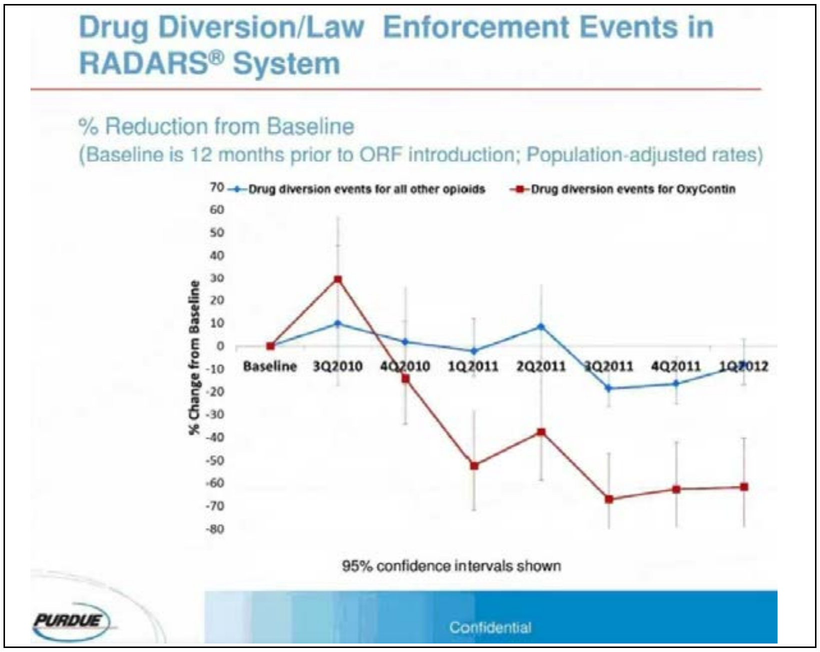


(Above) JX-2335 (June 2012 Presentation to Board) (PPLPC057000011194) at slide 9.



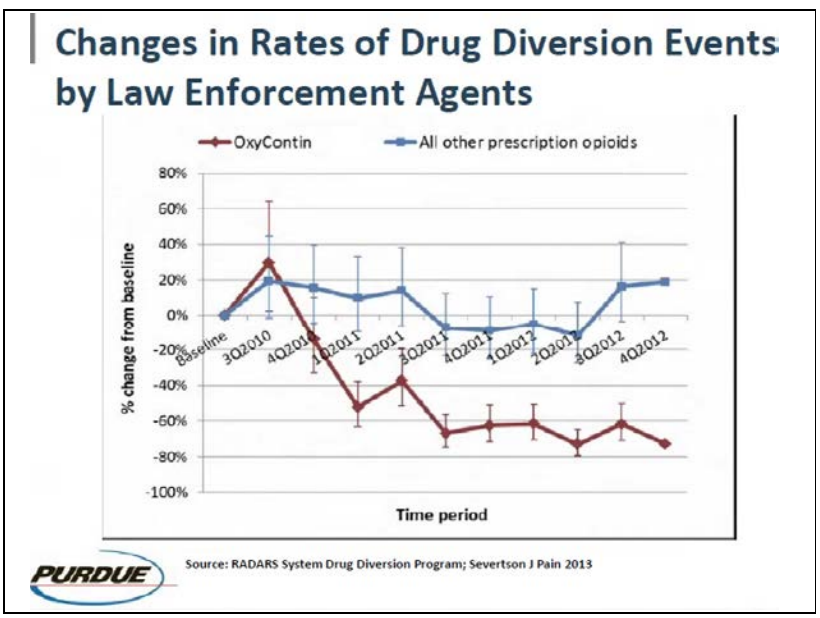
Id. at slide 11.

241. Management presented additional data documenting this reduction in diversion at the March 21, 2013 Board meeting, including this slide:



JX-2074 (Mar. 21, 2013 Board Agenda) (PPLPC044000041897) at -964.

242. Updated data showing substantial diminution in diversion were presented to Sackler family members at the November 16, 2013 beneficiaries meeting. *See, e.g.* JX-2381 (Nov. 16, 2013 Presentation to Beneficiaries) (PPLPC051000193984) at -4069:



243. **Positive DEA Reaction Reported to Board.** Purdue reported to the DEA

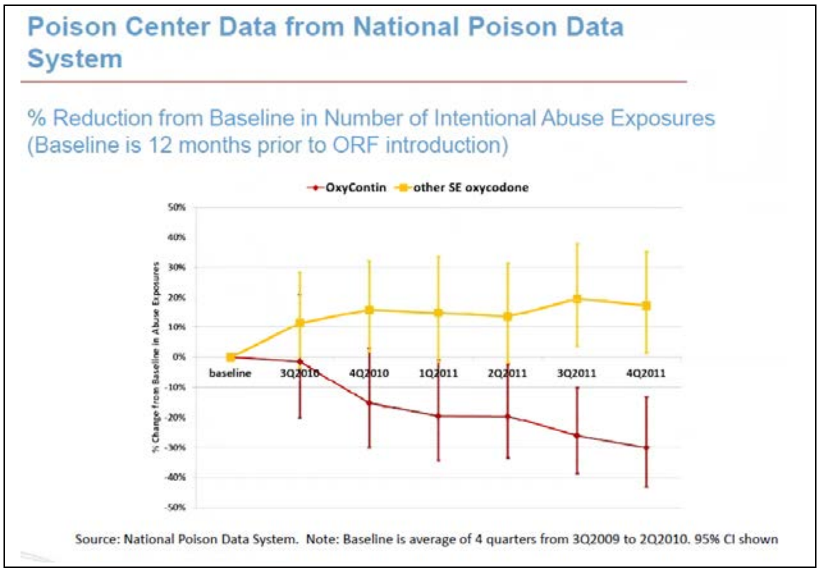
data showing that diversion fell substantially after ADF OxyContin was introduced.[367]

244. In November 2011, the Board was informed that the chief of the Regulatory Section of the DEA's Office of Diversion Control had reported to Purdue executives that the reformulation "*has made a tremendous difference*" and "*is saving lives*," and that the DEA "*[n]o longer hear[s] about OxyContin from field offices*."[368]

b. Reduction of Abuse

245. In addition to the drop in diversion, management also presented data to the Board showing a "Meaningful Reduction in Abuse" of OxyContin following introduction of the abuse-deterrent formulation.[369]

246. For example, at the March 21, 2013 Board meeting management presented, among others, the following three slides:



(Above) JX-2074 (Mar. 21, 2013 Board Agenda) (PPLPC044000041897) at -962.

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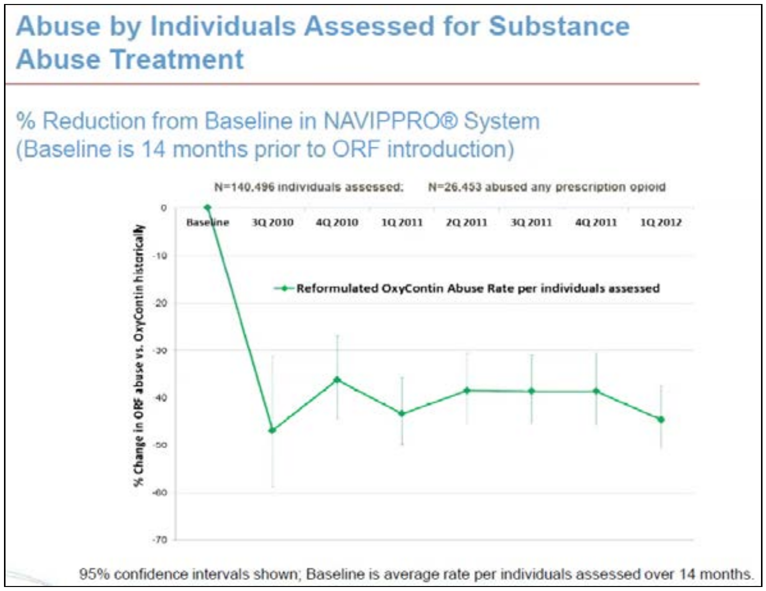
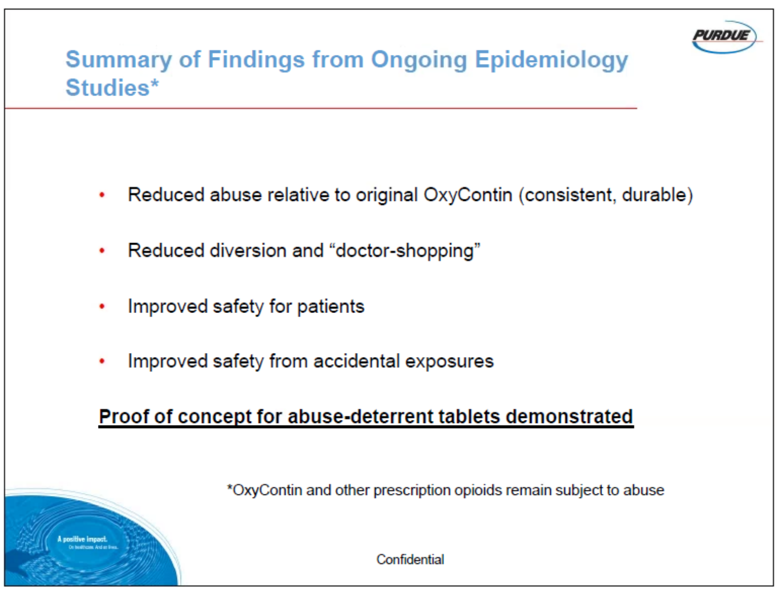
[367] JX-2325 (12/9/11 presentation entitled "Epidemiology studies of Reformulated OxyContin's effect on opioid abuse") (PPLPC019000618954).

[368] JX-2323 (Nov. 2011 Budget Book) (PPLPUCC9011086649) at slide 6.

[369] JX-2075 (July 25, 2013 Board Agenda) (PPLP004409781) at -860.



Id. at -961.



Id. at -968.

247. At management's November 16, 2013 beneficiaries' presentation to the Sackler family members, management presented additional data demonstrating the reduction in abuse. *See, e.g.*, JX-2381 (9/16/13 Presentation to Beneficiaries) (PPLPC051000193984) at -4067:

Reported abuse of OxyContin among abusers of any prescription opioid in the NAVIPPRO ASI-MV System
(June 2009 - Dec 2012)

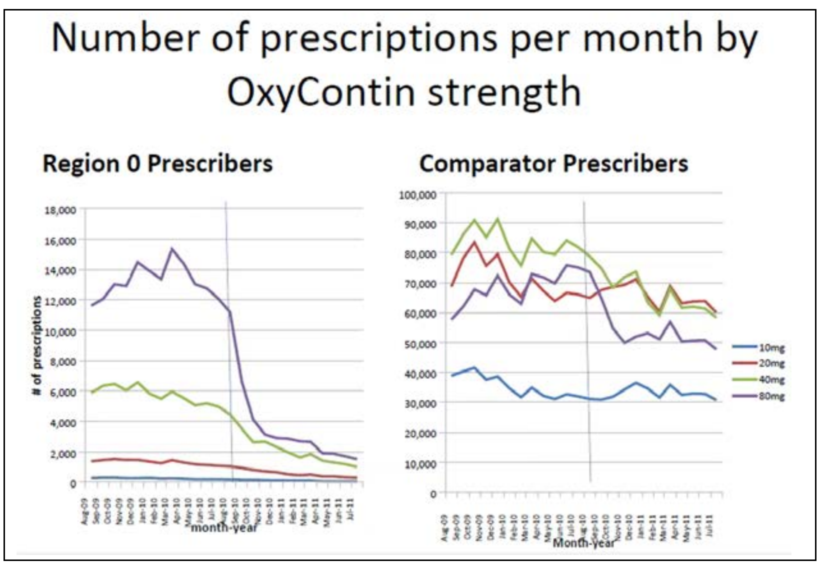
Original & Reformulated OxyContin	Before period (%)	After period (%)	Pre-post relative change	95% CI	P-Value
Any route	25	19	-24	(-27; -20)	<.0001
Oral	13	14	+2	(-3, 8)	0.432
Non-Oral	19	11	-42	(-45, -38	<.0001

Before period = June 2009 through August 8, 2010
† After period = August 9, 2010 through December 31, 2012 Only ORF (and not OC) is included in this column.

c. Reduction in Prescriptions By Region Zero Prescribers

248. While Purdue stopped calling on (detailing) HCPs it placed on its Do Not Call/Region Zero list, Purdue could not prevent them from writing OxyContin—or any other—prescriptions.

249. Following the introduction of ADF OxyContin, the Board was informed that there was a sharp drop in the number of prescriptions written by Region Zero prescribers. This was reflected in data that management sent the Board with Executive Committee Notes dated October 11, 2011. *See, e.g.*, JX-2319 (Attachment to Oct. 25, 2011 Exec. Comm. Notes Sent to Board) (PURDUE-COR-0032186) at slide 12:



250. Having authorized the expenditure of a billion dollars on abuse deterrence,[370] the Board reasonably understood that the new formulation of OxyContin introduced in 2010 was having its intended, beneficial results. This was considered, in materials presented to the Board, as the "Positive Impact of AD [Abuse-Deterrent] OxyContin"[371] and proof that the concept of abuse deterrence worked in practice and validated the Board's support for the ADF strategy.[372]

6. In Setting Purdue's Quotas, Regulators Took into Account That OxyContin Was Subject to Abuse and Diversion

251. The DEA always considered the risk of diversion in setting quota allocations for OxyContin under the Controlled Substances Act.[373] For example:

- In the early 2000s, GAO reported that the DEA lowered the procurement quota requested by Purdue for OxyContin manufacturing "as a means for addressing abuse and diversion."[374]

- In 2009, a Drug Science Specialist at the DEA told Purdue employees that the company's "quota adjustment was assessed on many factors, including … diversion/abuse concerns."[375]

[370] *Select Initiatives Addressing the Crisis*, PURDUE PHARMA, https://www.purduepharma.com/addressing-the-crisis/select-initiatives/ (stating that "Purdue has spent approximately $1 billion to develop opioids with abuse-deterrent properties" and identifying other anti-diversion efforts by Purdue) (last visited July 16, 2021).

[371] JX-2075 (July 25, 2013 Board Agenda) (PPLP004409781) at -860.

[372] JX-2074 (Mar. 21, 2013 Board Agenda) (PPLPC044000041897) at -968 [redacted]. *See also* JX-2073 (Nov. 3, 2012 Purdue Presentation to Beneficiaries) (PPLP004409088) at -195 [redacted].

[373] 21 U.S.C. §826. The DEA sets production quotas and determines the supply of prescription opioids. The DEA can increase the annual production quota only if it determines that there is a legitimate medical need for that quantity of the drug. 21 C.F.R. §1303.11.

[374] U.S. Gen. Accounting Office, GAO-04-110, PRESCRIPTION DRUGS: OXYCONTIN ABUSE AND DIVERSION AND EFFORTS TO ADDRESS THE PROBLEM 38 (2003), *available at* https://www.gao.gov/assets/250/240884.pdf.

[375] JX-2273 (8/4/09 Email Thread between Purdue and DEA) (PWA001036221) at -223.

252. At the same time, while taking abuse and diversion into consideration in setting quotas, DEA recognized that there are competing considerations: "[A] reduction in the supply of a drug based upon estimated illegitimate prescriptions or abuse and misuse could result in a shortage of the substance for legitimate purposes, while not affecting illicit demand for the substance at all," and, therefore, "the agency does not use the quota process as a tool to reduce demand or to help prevent abuse and misuse of prescription pain relievers."[376]

253. State regulators also understood both (1) that OxyContin was subject to abuse and diversion and (2) the need to calibrate those risks against the needs of legitimate pain patients.

a. In 2003, the National Association of Attorneys General ("**NAAG**") adopted a resolution that "called for a balanced approach to promoting pain relief and preventing abuse of pain medication."[377]

b. NAAG urged the DEA to be more accommodating to the needs of patients, recognizing that, "[o]n the one hand, there is the well-documented under-treatment of chronic pain, fueled, advocates argue, by the prosecutions of physicians; on the other, there is the well-documented increase in diversion of prescription medications that has led to ruined lives and death."[378]

c. The NAAG re-adopted the 2003 resolution in 2007, shortly before 27 of its members entered into Consent Judgments with Purdue requiring that the Company maintain its ADD Program.[379]

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376 U.S. Gen. Accounting Office, GAO-12-115, PRESCRIPTION PAIN RELIEVER ABUSE: AGENCIES HAVE BEGUN COORDINATING EDUCATION EFFORTS, BUT NEED TO ASSESS EFFECTIVENESS 50-51 (2011), *available at* https://www.gao.gov/assets/590/587301.pdf.

377 *See* Judy McKee, *Finding the Proper Balance: Walking the Tightrope Between Treating Chronic Pain and Countering Prescription Drug Diversion*, NAAGAZETTE, (Jul. 30, 2008) https://web.archive.org/web/20170806023733/https://www.naag.org/publications/naagazette/volume-2-number-7/finding-the-proper-balance-walking-the-tightrope-between-treating-chronic-pain-and-countering-prescr.php.

378 *Id.*

379 *Id.*

V. NONE OF THE FORMER DIRECTORS CONTROLLED PURDUE OR ITS MANAGEMENT DURING THE RELEVANT PERIOD

254. Throughout the Relevant Period, PPLP was indirectly beneficially owned by Side A and Side B, with Side B's half owned by certain trusts for the benefit of members of the Raymond Sackler Family.[380] Ownership of Side B's half of PPI was further divided equally between two entities created in 2003—Linarite Holdings LLC and Perthlite Holdings LLC—which were owned by certain trusts created in 2002 as divisions from trusts created in 1989.[381]

255. The Sackler Families, through indirect 100% ownership of PPI and PPLP, collectively possessed control of PPLP, but no individual Sackler Family Member controlled Purdue or its management, and neither Side A nor Side B, alone, could dictate any Board decision.

A. PPLP's Day-To-Day Business Was Managed by Its Officers

1. The Former Directors Acted in Accordance with Their Responsibilities as Directors

256. During the Relevant Period, Former Directors Richard, Jonathan, David and Beverly Sackler sat on the Board of PPI, but no Sackler Family Member served as an officer of PPI or PPLP.[382]

257. PPI currently has no equity interest in PPLP, which is 100% owned by PPLP's

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[380] *See* JX-1915 (Martin Report, Ex. A — 11/2019 Raymond-Side Informational Presentation) at slides 28, 29, 78 and 79.

[381] *See* JX-1915 (Martin Report, Ex. A — 11/2019 Raymond-Side Informational Presentation) at slides 28, 29, 78 and 79.

[382] *See* JX-2090 (Purdue Directors List) (PPLPUCC500140094); JX-2093 (Purdue's Responses and Objections to Plaintiff's First Set of Interrogatories, *People of the State of New York v. Purdue Pharma L.P., et al.*, No. 400016/2018 (N.Y. Sup. Ct., Suffolk Cnty. Dec. 20, 2018)) at 15–33.

limited partner, PRALP, a Delaware limited partnership.[383] Instead, PPI receives a fee for services to PPLP.[384]

258. The indirect owners, as owners, had no authority to manage Purdue's business.

259. Under the PPI By-Laws, the PPI Board's authority was reserved for "[a]ll substantive matters not in the day-to-day ordinary course of business."[385]

260. These "matters" included enumerated issues, such as approval of budgets; introduction of new products; product and intellectual property rights acquisitions costing more than 1% of gross margin of the acquiring entity; and election, engagement, compensation, and termination of senior officers.[386] The PPI board held regular meeting, as reflected by the board minutes and decision documents in its corporate records.[387]

261. Matters regarding Purdue's day-to-day business were delegated to, and handled by, Purdue's management.

a. An internal Purdue document entitled "**Governance Process**" states: "<u>Purdue operates its business under the direction of the Purdue management team</u> subject to Board approval of (1) Annual Budget, (2) Business Development Opportunities/Investments, (3) Financings, (4) Facilities decisions"[388]

b. Another Purdue business record—a Power Point presentation entitled "**Purdue**

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383 In 2006, PPI was assigned a .25% interest in PPLP, which was reduced to .2475% in 2008 and 0% in 2010. *See* JX-2088 (2018 LPA) (PUT000010556) at 2–3; JX-2089 (2019 LPA amendment) (PPLPUCC500143435). *See also* JX-1902 (AlixPartners Cash Transfers of Value Analysis, Dkt. No. 654-1), Appendix C.

384 JX-2079 (1997 LPA) (PDD9316726090) §23; JX-2088 (2018 LPA) (PUT000010556) §24.

385 JX-2084 (PPI By-Laws Annex I) (PUT000010519) at -548.

386 *Id*.

387 *See, e.g.*, JX-2023 (10/19/09 PPI Minutes) (PPLP004415611); JX-2029 (2/3/11 PPI Minutes) (PPLP004415797); JX-2034 (1/19/12 PPI Minutes) (PPLP004415845); JX-1912 (2/16/11 Decision Document) (PPLP004417142).

388 *See* JX-2009 (11/4/20 S. Baker Dep. Tr.) at 162:4–9.

Committees"—states: "Under the direction of the Board, the Executive Committee is the primary governance and decision-making body at Purdue. The Executive Committee sets overall product and organizational direction and strategy (including identifying new therapeutic areas to enter, product development and acquisition opportunities to pursue and significant changes to business processes), and devises and oversees processes to manage critical events." [389]

c. PPI's By-Laws provided that: [redacted].[390]

d. Parallel provisions in the By-Laws conferred authority on Senior Vice Presidents, Executive Vice Presidents, Vice Presidents and other officers.[391]

262. Under the PPI Bylaws, Purdue executives were required to "report to the President and CEO," not to the Board, "except for matters related to the shareholders, Board of Directors or its Committees, where the Executive Vice President, Counsel to the Board shall report as otherwise agreed."[392]

263. The PPI By-Laws charged Purdue's President and CEO with "ensur[ing] that the Board of Directors receives all information necessary on a current basis in order to enable the Board of Directors to be informed of all major events and matters that alone or in the aggregate would have a material effect on the business, assets, operations or condition, financial or otherwise, or prospects of the Partnership."[393]

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[389] JX-2253 (May 2011 Purdue Committees Presentation) (PPLPC012000378037) at slide 5.

[390] JX-2084 (PPI By-Laws) (PUT000010519) art. III, §5(ii)(E), at -535; *see id.* at -548 (Annex 1: "MATTERS RESERVED TO THE BOARD").

[391] *Id.* art. III, §5(iii)–(vii), at -535–536.

[392] *See id.* at -534. Under the Compliance Charter, the Vice President of Corporate Compliance reported directly to the President and CEO and, on at least a quarterly basis, to the Board. JX-1892 (May 11, 2007 Compliance Charter) (PPLP004416592) at -594–595.

[393] *See* JX-2084 (PPI By-Laws) (PUT000010519) art. III, §5(ii)(C), at -534–35.

264. The actual task of running Purdue on a day-to-day basis was in the hands of Purdue's executives, who oversaw a workforce of 1,100 to more than 1,600 employees for most of the Relevant Period.[394]

265. Numerous witnesses confirmed that the Former Directors had scant contact with Purdue personnel outside of board meetings. *See, e.g.*:

- Purdue's Director of Advocacy in Public Affairs Department, then Executive Director of Healthcare Alliance Department, who worked at Purdue from 2001–2018, testified that she met the Sacklers "once or twice" in her 18 years at Purdue at board meetings and a holiday party.[395]

- Purdue's Senior Director of Research & Development from 2000 onwards testified that "the only meetings that I had that included Dr. Richard ... were board meetings, where I was as the head of regulatory or even before then as the head of a particular project reporting to the board on development programs."[396]

- An executive in charge of Government Relations, when asked whether Richard Sackler was "involved in setting up the Pain Care Forum," testified: "Not at all, to my knowledge. … I don't think I ever had a personal conversation with Richard about the Pain Care Forum, none that I can remember.… I might have mentioned the Pain Care Forum at a board meeting."[397]

- One executive who worked at Purdue for over 25 years, for most of her tenure as Director of Product Monitoring, was asked during her deposition "was Richard Sackler involved in the day-today management of the company, of Purdue in your experience?" She testified "In my experience, I had very little to do with him."[398]

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394 *See* JX-2049 (1Q 2008 Board Report) (PPLP004367134) at -156 (1,199 total employees); JX-2052 (1Q 2009 Board Report) (PPLP004367262) at -289 (1,367 total employees); JX-2057 (2Q 2010 Board Report) (PPLP004367018) at -045 (1,417 total employees); JX-2692 (1Q 2011 Board Report) (PPLPC012000322426) at -461 (1,636 total employees); JX-2062 (1Q 2012 Board Report) (PPLPC012000374791) at -823 (1,644 total employees); JX-2068 (4Q 2013 Board Report) (PPLPC002000181035) at -081 (1,690 total employees).

395 JX-2004 (1/16/19 Pamela Bennett MDL Tr.) at 29:4–9, 115:18–21, 116:19–23 237:22–239:11.

396 JX-1999 (12/6/18 Richard Fanelli MDL 30(b)(6) Tr. Vol. I) at 314:18–316:4; JX-2000 (12/7/18 R. Fanelli MDL 30(b)(6) Tr. Vol. II) 427:22–428:2, 430:8–9.

397 JX-2005 (1/16/19 Burt Rosen MDL Dep. Tr.) at 27:22–28:2, 39:12–13, 65:1–16, 302:20–22.

398 JX-2001 (12/10/18 Lee Ann Storey MDL Dep. Tr.) at 28:2–29:3, 44:14–45:15; 88:14–90:10.

2. No Individual Director or Class Of Directors Controlled the Board

266. No single director or class of directors (Side A or Side B) was empowered to compel Board action during the Relevant Period.

- 500 Class A and 500 Class B shares were owned, respectively, by Side A and Side B.[399]
- Class A shareholders appointed some of the directors (the "**Class A Directors**"), and Class B shareholders appointed the remainder (the "**Class B Directors**").[400]
- A quorum "of not less than one-third of the entire [PPI] Board" was necessary "for the transaction of any and all business of the Board," and the PPI Certificate of Incorporation required that the quorum include a specified minimum presence of Class A and B Directors.[401]
- The PPI Certificate of Incorporation specified that "[a]ll actions by the Board … shall be approved by" a majority of the Class A Directors and a majority of the Class B Directors present at the meeting.[402]

267. In each year from 2007 through February 2018 (when Purdue stopped marketing

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[399] *See* JX-2083 (3/3/03 PPI Restated Certificate of Incorporation) (PKY180173691)-696–98. On Side B, the ownership of the Class B shares was divided between Linarite Holdings LLC ("**Linarite**"), which is owned by a trust for the benefit of the issue of Jonathan Sackler, and Perthlite Holding LLC ("**Perthlite**"), which is owned by a trust for the benefit of the issue of Richard Sackler. *See* JX-2086 (1/21/10 Amendment to Shareholder Agreement) (PPLP004415716); JX-1915 (Martin Report, Ex. A — 11/2019 Raymond-Side Informational Presentation) at slides 28–29, 78–79, and Supp. at slide 2.

[400] The PPI Certificate of Incorporation provided that Class A and Class B PPI shares each "shall vote separately as a class in connection with the election of [PPI] Directors." *See* JX-2087 (PPI Certificate of Amendment of Certificate of Incorporation of PPI)) (PPLP004415886) at -888–89; JX-2085 (4/18/08 Amendments to By-Laws) (PPLP004415363) ("**Amendments to By-Laws**") at -370 (amending art. IX, §2(ii)).

[401] *See* JX-2087 (PPI Certificate of Amendment of Certificate of Incorporation of PPI) (PPLP004415886) at -888–89 (amending art. IIII). *See also* JX-2085 (Amendments to By-Laws) (PPLP004415363) at -372 (amending art. IX, §3(i)(A).

[402] *See* JX-2083 (3/4/03 Restated Certificate of Incorporation of PPI) (PKY180173691) at -698 (art. III); JX-2087 (PPI Certificate of Amendment of Certificate of Incorporation of PPI) PPLP004415886) at -889 (amending art. III). *See also* JX-2085 (Amendments to By-Laws) (PPLP004415363) -373 (amending art. IX, §3(i)(B).

its opioid products), the Board included no fewer than 4 Class B Directors and 5 Class A Directors:[403]

YEAR	TOTAL CLASS B DIRECTORS	TOTAL CLASS A DIRECTORS	TOTAL DIRECTORS
2007	4	5	9
2008	from 4 to 6	5	from 9 to 11
2009	5	From 5 to 6	From 10 to 11
2010	5	from 6 to 7	from 11 to 12
2011	5	6	11
2012	from 5 to 8	6	from 11 to 14
2013	8	6	14
2014	8	6	14
2015	8	5	13
2016	8	From 5 to 6	From 13 to 14
2017	from 5 to 8	6	from 11 to 14
Through Feb. 2018	from 4 to 5	6	from 10 to 11

268. The Class A and Class B directors included several highly-credentialed outside directors during the Relevant Period, among them:

- **Ralph Snyderman MD** (Class B), Former Chancellor for Health Affairs and Former Dean of the Medical School of Duke University. Dr. Snyderman had served on the boards of numerous other pharmaceutical and biotech companies, including Trevena, Inc., Targacept, Liquida Technologies, CareDx, Inc. and Procter & Gamble Company.[404]

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403 JX-2090 (Purdue Directors List) (PPLPUCC500140094).

404 Ralph Snyderman, MD, DUKE UNIVERSITY SCHOOL OF MEDICINE, https://medicine.duke.edu/faculty/ralph-snyderman-md (last visited Mar. 29, 2021); Ralph Snyderman, M.D., iRhythm, https://investors.irhythmtech.com/board-member/ralph-snyderman-md (last visited July 28, 2021).

- **Judy Lewent** (Class A), former CFO of Merck & Co. and former President of Merck's Human Health Asia Division. Ms. Lewent had also served on the boards of numerous technology, food, and health science companies, including GlaxoSmithKline PLC, Dell Inc., Quaker Oats Company, Motorola Inc., Motorola Solutions Inc., and Thermo Fisher Scientific Inc.[405]

- **Cecil Pickett** (Class A), former Corporate Senior Vice President of Schering-Plough Corp., Senior Vice President and President of Schering-Plough Research Institute. Mr. Pickett had also served on the boards of Idec Pharmaceuticals Corp. and Biogen Idec Inc.[406]

- **Peter Boer** (Class B), President and CEO of Tiger Scientific Inc. Mr. Boer was a former executive at W.R. Grace & Co., and also served as a director of NOVA Chemicals Corporation, ENSCO, Inc., W.R. Grace & Co., and Chomerics, Inc.[407]

- **Paulo Costa** (Class B), former: President of Janssen Pharmaceuticals, Inc. US, Executive Vice President of Global Franchise Development, of Johnson & Johnson, and President and CEO of Novartis Pharmaceuticals. He also served as the Chair of the Board of Amylin Pharmaceuticals, Inc. and was a member of the board of MacroGenics, Inc.[408]

269. In determining whether Board action had been approved by a majority of the Class A and Class B Directors at a meeting, the votes of the outside directors in each Class were computed.

270. The evidence shows that the directors—both between and among Class A and

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[405] Judy Lewent, GLAXOSMITHKLINE, https://web.archive.org/web/20210227181821/https://www.gsk.com/en-gb/about-us/board-of-directors/judy-lewent/ (last visited July 28, 2021); Judy Lewent, Motorola Solutions, https://newsroom.motorolasolutions.com/executive-biographies/board-directors/judy-c-lewent.htm (last visited July 28, 2021).

[406] Cecil Pickett, Am. Assoc. for Cancer Research, https://www.aacr.org/governance/cecil-b-pickett-phd/ (last visited Mar. 29, 2021); Cecil B. Pickett, Bloomberg, https://www.bloomberg.com/profile/person/4927281 (last visited July 28, 2021).

[407] About F. Peter Boer, Tiger Scientific Inc., http://www.boer.org/bio.shtml (last visited July 28, 2021); JX-2479 (F. Peter Boer, Curriculum Vitae) (PPLPUCC9003818077).

[408] Paulo Costa, MacroGenics, http://ir.macrogenics.com/board-directors/paulo-costa (last visited July 28, 2021); Paulo Costa, Twst.com, https://www.twst.com/bio/paulo-costa/ (last visited July 28, 2021).

Class B—frequently did not vote together. For example:

- Outside Director Cecil Pickett testified: "[S]ometimes there were differences between the family members … disagreements within families and within the family members, both sides of the families.... The A side probably was more supportive of more distributions; where the B side was more supportive of putting money back in the company."[409]

- In 2011, Class A Director [redacted] voted yes on a [redacted] transaction, while Class A Directors [redacted] oted no.[410]

- In 2014, Class B directors wished to pursue and acquisition that the Class A directors opposed.[411]

- In 2014, Class B Directors Richard Sackler, David Sackler, [redacted] voted in favor of a proposed acquisition of Rye Pharmaceuticals, which Class B Directors Jonathan Sackler and [redacted] opposed.[412]

- In 2016, Class B Directors Jonathan Sackler, David Sackler, Paulo Costa, Ralph Snyderman and Peter Boer voted in favor of a proposed deal involving Exicure, while Class B Directors Richard Sackler voted against it.[413]

3. <u>"De-Facto CEO"</u>

271. Claimants contend that the Board acted as the "'de facto' CEO" of Purdue.[414]

272. The contention distorts the document from which the quoted phrase "'de facto' CEO" is drawn.

273. This phrase is clipped from a memo Craig Landau prepared when he was

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[409] JX-2008 (Cecil Pickett Dep. Tr.) at 140:25–141:6, 143:3–7.

[410] JX-2032 (Notes of August 2011 PPI Board meeting) (PPLPBN-00000963) at -966.

[411] JX-2417 (10/7/14 email from David Sackler to Jonathan Sackler) (PPLPUCC002907060).

[412] JX-2039 (Notes of October 2014 PPI Board meeting) (PPLPBN-00002063) at -2090.

[413] JX-2439 (Notes of October 2016 PPI Board meeting) (PPLPBN-00002815) at -834.

[414] *See*, *e.g.*, MA AG FAC ¶485; CT AG SAC ¶132; VT AG Compl. ¶362.

President of Purdue Canada—an IAC—for the board of MNP Consulting Limited ("**MNP**").[415]

274. The MNP board advised the IACs in 49 countries outside the U.S.—including Purdue Canada[416]—and did not advise PPLP or PPI.[417]

275. Landau's memo does not address PPLP, PPI, or the role of the PPI Board, or MNP's relationship with Purdue.

a. Landau's was one of several memos prepared in connection with a strategy session on the global pharmaceutical businesses of the Sackler families.[418]

b. All of the memos, including Landau's, proposed a global CEO to relieve the MNP Board.[419]

c. At the time the memos were written, Purdue (PPI and PPLP) had as its CEO, Mark Timney, an experienced pharmaceutical official who had previously

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415 JX-2448 (Landau Memo) (PWG004670880) (discussing "global investment strategy"); JX-2010 (11/24/20 Craig Landau Dep. Tr.) at 329:19-330:4 ("It was my understanding that [the memo] would ultimately … make its way to the board of directors ... it would be the MNP board.").

416 *See, e.g.*, JX-2010 (11/24/20 Craig Landau Dep. Tr.) at 295:12–15 ("Q. Who did you report to as CEO of Purdue Canada? A. My understanding was that I reported to the MNP board."); JX-2444 (MNP Board Agenda) (PPLPUCC9002689883) at -038 (proposed decision by MNP Board concerning Purdue Canada budget).

417 A document produced in discovery appears to reflect a recommendation by the MNP Board to PPLP. *See* JX-2282 (Feb. 2010 MNP Decision Compilation Excerpt) (PPLP004417012) at -018. Stuart Baker—longtime outside counsel and adviser to the Sackler families; an officer of PPI, PPLP and MNP; an officer and/or director of IACs; and the person who chaired meetings of the PPI and MNP Boards—testified that this document was a mistake and that the MNP Board did not make decisions about or recommendations to Purdue. JX-2009 (Stuart Baker Dep. Tr.) at 332:10–12 ("I see that and I'm telling you that as I sit here today and look at it, it's a mistake."); *see generally id.* at 330:5–334:7; 306:25–307:18 (discussing JX-2282 (Feb. 2010 MNP Decision Compilation Excerpt) (PPLP004417012)); JX-2474 (Baker Ex 24) at Ex B. No contrary evidence has been adduced.

418 JX-2448 (Landau Memo) (PWG004670880) at -880 ("The global Sackler pharmaceutical enterprise is at an inflection point...."), -881 ("Collectively, the IACs are pursuing too many therapeutic areas....").

419 *See, e.g.*, JX-2449 (5/5/17 Memo from Mark Timney) (PPLPC051000317758) at -763–64; JX-2450 (5/15/17 Memo from Raman Singh) (PPLPC051000317750) at -752–53); JX-2452 (5/26/17 Email attaching David Lundie Memo) (PPLPUCC9003936540) at -545.

worked in senior executive positions at Merck & Co., including President US, President Japan and President of Global Primary Care. [420]

VI. DURING THE RELEVANT PERIOD, THE FORMER DIRECTORS DID NOT PARTICIPATE IN DECISIONS ABOUT WHAT PURDUE'S MARKETING WOULD SAY, BUT UNDERSTOOD THAT IT WAS LAWFUL AND WAS TARGETED AT A LEGITIMATE MARKET

276. Claimants advance the theory that Purdue, under the control of the Former Directors, engaged in the deceptive marketing and promotion of OxyContin and other opioids.[421]

277. Unrefuted evidence establishes that—before any marketing material could be used—the Legal, Medical and Regulatory Affairs Departments were required to review and unanimously approve it.[422]

278. Claimants have been produced in excess of 100 million pages of documents and have taken 16 depositions of Sackler Family Members, current and former PPI Board members, Purdue employees and other Persons.[423]

279. No evidence has been adduced that any Former Director participated in the

[420] Krishna Gorti, *The Medicines Company Appoints Mark Timney as Chief Executive*, BIOSPACE (Dec. 11, 2018), https://www.biospace.com/article/releases/the-medicines-company-appoints-mark-timney-as-chief-executive-officer/.

[421] *See, e.g.*, First Amended Complaint ¶349, *New York v. Purdue Pharma L.P.*, No. 400016/2018 (N.Y. Sup. Ct., Suffolk Cnty. June 18, 2019) ("**NYAG FAC**") (JX-2211) ("Purdue's deliberate actions to mislead prescribers and the public about the risks and benefits of long-term opioid treatment were orchestrated by the Sacklers from the launch of OxyContin through the present"); Complaint ¶8, *State of Rhode Island v. Sackler.*, No. PC-2019-9399 (R.I. Sup. Ct., Providence Cnty. Sept. 11, 2019) ("**RI v. Sackler OC**") (JX-2214) ("[T]hey always held the controlling majority of the Board, which gave them full power over both Purdue Pharma Inc. and Purdue Pharma L.P. They directed deceptive sales and marketing practices within Purdue . . . ."); First Amended Complaint at 111, *Colorado v. Purdue Pharma L.P.*, No. 18CV33300 (Colo. Dist. Ct., Denver Cnty. July 1, 2019) ("**CO AG FAC**") (JX-2212) ("THE SACKLERS CONTROLLED, DIRECTED, PARTICIPATED IN, AND/OR SANCTIONED DEFENDANTS' DECEPTIVE AND RECKLESS OPIOID BUSINESS").

[422] *See* JX-1872 (Nov. 2007 Material Review Process SOP) (PPLP004368497) at -498–99.

[423] *See* Disclosure Statement for Fifth Amended Joint Chapter 11 Plan of Reorganization of Purdue Pharma LP And Its Affiliated Debtors (Dkt.2983) at 59, 86.

drafting, or approved the content, of any Purdue marketing material during the Relevant Period.

280. No evidence has been adduced that the PPI Board voted on the contents of Purdue's marketing during the Relevant Period.

281. No evidence has been adduced that, during the Relevant Period, the Former Directors were asked to participate in decisions, or make suggestions, about what Purdue's marketing should say.

282. No evidence has been adduced that, during the Relevant Period, any piece of Purdue marketing was changed or adopted because of any Board decision or the input of any PPI Board member.

283. No evidence has been adduced that any Former Director directed or encouraged any misstatement.

284. No evidence has been adduced challenging the reasonableness of the Former Directors' reliance on:

a. Approval of all marketing material by the Legal, Medical, and Regulatory Affairs Departments.

b. Outside counsel's reviews and positive endorsements of Purdue's Compliance Program.

c. The OIG's and IRO's confirmations of Purdue's compliance with the CIA from July 31, 2007 through July 30, 2012.

d. Management's detailed compliance reports and confirmations that Purdue's marketing complied with state and federal law throughout from May 2007 through December 2018.

e. Monitoring of sales representatives' calls on HCPs by District Managers and the Legal and Compliance Departments.

f. Compliance audits of key risk activities by management.

285. Notes from a Purdue Executive Committee remark that "the Board ha[d] little opportunity" outside of budget meetings "to see the detailed work of the Sales and Marketing

group...." [424]

286. David Sackler testified that "management would make presentations to the board on sales and marketing," but "there wasn't a lot of feedback given."[425]

A. The Former Directors Did Not Participate in Purdue's Marketing During the Relevant Period

287. In the absence of any direct evidence that the Former Directors participated in Purdue's marketing during the Relevant Period, Claimants point to certain documents to contend that the Former Directors micromanaged Purdue's day-to-day business, and from this urge an inference that the Former Directors participated in Purdue's marketing. The cited documents do not support the contention or the inference.

1. Board Communications

a. Board Reports

288. Claimants assert that, because the Former Directors received certain Board Reports from management that discussed Purdue's operations, including sales and marketing, the Board was involved in decisions about what Purdue's marketing would say.[426]

289. The evidence establishes that the Former Directors received information from management on Purdue's operations, including sales and marketing, posed questions to

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[424] *See* JX-2262 (11/12/08 Executive Committee Notes) (PPLPC053000030108) at -109.

[425] JX-1989 (8/28/20 David Sackler Dep. Tr.) at 245:6–17.

[426] *See, e.g.*, MA AG FAC ¶335 (citing JX-2059 (4Q 2010 Board Report) (PPLP004366955)), ¶433 (citing JX-2068 (4Q 2013 Board Report) (PPLPC002000181035)); NYAG FAC ¶391 (quoting JX-2059 (4Q 2010 Board Report) (PPLP004366955)), ¶392 (referencing JX-2705 (August 2011 Board Report) (PPLP004366913)), ¶398 (quoting JX-2068 (4Q 2013 Board Report) (PPLPC002000181035)). *See also, e.g.*, VT AG Compl. ¶¶115, 118, 120–21 (citing JX-2046 (2Q 2007 Board Report) (PPLP004366645)); ¶123–24 (citing JX-2047 (3Q 2007 Board Report) (PPLPC012000157402)); ¶¶127–28 (citing JX-2048 (4Q 2007 Board Report).

management, and voted to ratify or reject management's proposals, but no evidence has been adduced that any of the Board Reports—or any other communication—solicited the Former Directors' participation in decisions about what Purdue's marketing should say.

290. The Claimants' allegations are also refuted by the very documents they cite or rely on. For example, Claimants assert that certain Board Reports show that the Former Directors oversaw Purdue's strategy to pay high prescribers to promote Purdue's opioids."[427]

- The cited Board Reports say nothing about a strategy to pay high prescribers"—they informed the Board of new reporting requirements and spending limits under the "Sunshine Act"[428] and advised the Board that Purdue's speaker programs had "appropriate controls," including "a live monitoring process" and an "expert consultant on Fair Market Valuation compensation of speakers," to ensure compliance.[429]

291. Claimants cite certain Board Reports as evidence that the Former Directors "oversaw Purdue's strategy to push patients to higher doses of opioids."[430]

- The cited Board Reports say nothing about pushing patients to higher doses. They informed the Board that net sales were declining.[431]

- The cited Board reports were issued in 2011, and the OIG of HHS confirmed

[427] MA AG OC ¶182. MD SOC ¶264.

[428] JX-2066 (2Q 2013 Board Report) (PPLPC012000433388) at -436.

[429] JX-2705 (2Q 2011 Board Report) (PPLP004366913) at -940; *see also* JX-2060 (3Q 2011 Board Report) (PPLP004366871) at -897 ("implemented a live monitoring process. Approximately 10% of all speaker programs have an independent monitor in attendance to identify and report any compliance issues. To date no substantive concerns have been identified.").

[430] MA AG OC ¶183. *Cf.* NY AG FAC ¶388; CT AG SAC ¶¶35, 47; MD SOC ¶¶122, 265; CA AG FAC ¶39.

[431] *See* JX-2059 (4Q 2011 Board Report) (PPLP004366955) at -957 [redacted]; JX-2705 (2Q 2011 Board Report) (PPLP004366913) at -915 [redacted].

Purdue's compliance with its Corporate Integrity Agreement in 2011.[432]

292. Claimants allege, relying on specific Board Reports, that the directors "oversaw Purdue's push to steer patients away from safer alternatives."[433]

- The cited Board Report had nothing to do with a marketing "push" away from safer alternatives. It explained why some insurers would not cover Hysingla, an as-yet unlaunched product.[434]

293. Claimants contend that the "Sacklers directed Purdue to hire hundreds of sales representatives to carry out their deceptive sales campaign.…"[435]

- The underlying Board Report merely informs the Board that Purdue had expanded its sales force in connection with the upcoming launch Purdue's new product, Butrans.[436]
- This Board Report was issued in 2011, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2011.

294. Claimants cite a Board Report ostensibly to show that the Board "agreed" to "a 'Key Initiative' ... to get patients to stay on therapy longer."[437]

- Claimants' citation is a juxtaposition of unrelated portions of a 48-page Board Report, one of which discussed net sales (p. 3) and the other of which explained an

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[432] *See* JX-2059 (4Q 2011 Board Report) (PPLP004366955) at -957 [redacted]; JX-2705 (2Q 2011 Board Report) (PPLP004366913) at -915 ("2Q 2011 year to date net sales … were lower than budget … mainly due to declining sales in the 40 mg and 80 mg strengths.").

[433] MA AG OC ¶188. *Cf.* NY AG FAC ¶388; MD SOC ¶272; CT AG SAC ¶28.

[434] JX-2351 (6/6/13 Managed Care Board Slides) (PPLPC063000016119) at -137 ("HYD Payer Research … Payers will not value a new hydrocodone product until they more fully understand the true incidence of opioid combination acetaminophen-related liver toxicity.").

[435] NY AG FAC ¶394. *See also* CT AG SAC ¶1433(c) & (j); MD SOC ¶108; DE AG Compl. ¶50; VT AG Compl. ¶107.

[436] JX-2059 (4Q 2010 Board Report) (PPLP004366955) at -960.

[437] NY AG FAC ¶398; *see also* MA AG FAC ¶433; CT AG SAC ¶¶27, 35; MD SOC ¶267; CA AG FAC ¶39.

adherence program to help patients take Butrans as prescribed (pp. 9–10, 22).

- The Board Report also informed the Board that Purdue "continue[d] to maintain a state of effective compliance" (p. 39).[438]

b. Documents Related to Butrans (A Schedule III Patch)

295. Claimants do not distinguish, in their contentions concerning Purdue's marketing, between the marketing of OxyContin (a Schedule II pill) and Butrans (a Schedule III patch).

296. Although OxyContin and Butrans are both opioids, they are substantially different:

a. No evidence has been adduced linking the Butrans patch with the opioid crisis.

b. Butrans is a skin patch that contains buprenorphine, not oxycodone.

c. Buprenorphine is a Schedule III controlled substance that is subject to less strict regulation than Schedule II opioids like OxyContin because it has a lower potential for abuse or dependence.[439]

d. According to the federal Substance Abuse and Mental Health Services Administration, "buprenorphine has unique pharmacological properties that help: diminish the effects of physical dependency to opioids, such as withdrawal symptoms and cravings; increase safety in cases of overdose; [and] lower the potential for misuse."[440]

e. Unlike OxyContin,[441] Butrans has a ceiling dose—the FDA-approved label for

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[438] JX-2068 (4Q 2013 Board Report) (PPLPC002000181035) at -037, -043–44, -056, -073.

[439] *See Drug Scheduling*, DRUG ENFORCEMENT ADMINISTRATION, https://www.dea.gov/drug-scheduling (last visited on July 28, 2021).

[440] *See Buprenorphine*, U.S. DEP'T OF HEALTH & HUMAN SERVS., SUBSTANCE ABUSE & MENTAL HEALTH SERV. ADMIN., https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/buprenorphine (last updated May 14, 2021).

[441] *See* JX-2122 (March 2021 Label) at 36 ("Like all full opioid agonists, there is no ceiling effect to analgesia for oxycodone."), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022272s046lbl.pdf.

Butrans sets the upper limit for a Butrans prescription at 20mcg/hour.[442]

f. Many Claimants contend that Purdue sought to convince HCPs to prescribe "higher and higher doses" of opioids.[443] These allegations do not fit Butrans, with its ceiling dose—higher and higher doses could not be prescribed.

297. Without distinguishing Butrans from OxyContin, the 2010 Board Report has been cited for the proposition that Purdue management told the Board that "sales reps would try to switch patients to opioids from NSAIDs."[444]

- The cited presentation informed the Board that the "proposed placement in clinical practice" for Butrans included patients for whom NSAIDs were not working because "pain is not well controlled" using an NSAID, or an "NSAID … [is] not tolerated."[445]

- The presentation also informed the Board that Purdue would provide prescribers "[a]ppropriate fair balance information … including contraindications, warnings, precautions and safety information," and would "[p]roperly educate healthcare professionals on … [t]he full prescribing information and appropriate use of Butrans."[446]

- The presentation was given to the Board in 2010, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2010.

298. Some Claimants have cited a 2011 email for the proposition that the Board was informed that Purdue sales representatives focused on physicians that "would be most susceptible to sales reps lobbying to prescribe more opioids" and "push[ed] opioids for elderly

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[442] JX-2130 (2014 Butrans Label) at 5 ("The maximum BUTRANS dose is 20 mcg/hour. Do not exceed a dose of one 20 mcg/hour"), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021306s015s019lbl.pdf.

[443] *See, e.g.*, MA AG FAC ¶¶67, 857; CT AG SAC ¶¶35, 47; MD SOC ¶¶122, 265; CA AG FAC ¶39.

[444] MA AG FAC ¶306. *Cf.* VT AG Compl. ¶198.

[445] JX-2289 (7/22/10 Butrans Commercial Strategy Plan Board Presentation) (PPLPC018000404193) at slide 17.

[446] *Id.* at 20, 46.

patients with arthritis."[447]

- The cited email does not mention "arthritis," "pushing opioids," or the "susceptibility" of physicians.[448]

- The email informed the Board that Purdue was focused on Butrans "and what need[ed] to be done to increase [its] growth" after its launch earlier that year.[449]

- The email advised that Purdue was working to grow Butrans sales by "[i]mproving physician targeting," "[i]ncreasing call frequency", and "[i]mprov[ing] specific patient focus on calls."[450]

- The email was sent to the Board in 2011, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2011.

299. Some Claimants have alleged that Purdue staff told Richard Sackler in March 2012 that Purdue was "pushing opioids for elderly patients with arthritis ("proper patient selection") and encouraging doctors to use higher doses of opioids ("quick titration")."[451]

- The cited email does not mention the elderly, arthritis or encouraging doctors to use higher doses of opioids.

- The email says that Butrans sales statistics had improved and that David Rosen guessed "the breakthrough … is related to the messages coming out of the district meetings and [their] renewed discussion around proper patient selection, supplemental analgesia and quick titration."[452]

- The email was sent in March 2012, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement for this period.

300. No evidence has been adduced that Purdue marketed Butrans improperly.

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[447] MA AG FAC ¶¶341–42. *See also* DE AG Compl. ¶158; VT AG Compl ¶ 228.

[448] JX-2305 (5/25/11 Email to Board) (PPLPC012000326017).

[449] *Id.*

[450] *Id.*

[451] MA AG ¶376. *See also* DE AG Compl. ¶¶158, 167; VT AG Compl. ¶¶226, 261; CT AG SAC ¶¶34, 51.

[452] JX-2332 (3/28/12 Email from David Rosen) (PPLPC012000371301).

c. McKinsey & Company's Advice

301. Some Claimants contend that the Former Directors engaged in misconduct by relying on advice they received from McKinsey & Company concerning what became Purdue's Evolve to Excellence ("**E2E**") marketing campaign.

302. Some Claimants maintain that the Board knew the legitimate market for Purdue's opioids had contracted following the introduction of ADF OxyContin, but nevertheless requested that management recapture those lost sales.[453]

303. Some Claimants allege that these requests led to E2E, "an aggressive marketing program" conceived by McKinsey in 2013 to detail over 100,000 prescribers, "including thousands of prescribers that the [Former Directors] knew or should have known were prescribing opioids that were not always for a medically accepted indication."[454]

304. The record does not support these allegations for at least eight reasons.

305. *First*, while the Claimants allege that the market for OxyContin had contracted, the unrefuted evidence establishes that there was a large legitimate market for OxyContin to pursue that was currently occupied by competitors.

306. The Board received an "Opioid Market Overview" presentation in November 2012—two years after ADF OxyContin was launched and the year before E2E was introduced—showing that the competitive prescription analgesic market totaled more than $12.1 billion, of which $8.2 billion consisted of opioid sales.[455]

307. Purdue's opioid sales were approximately $2.8 billion at that time. *Id.* at 3.

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[453] JX-2096 (10/21/20 Sackler Settlement with DOJ) at Addendum A ¶¶3, 56–71.

[454] *Id.* ¶¶4, 78.

[455] JX-2342 (10/25/12 Email Attaching Sales & Mktg. Presentation to Board) (PPLPC012000396109) at slide 8.

308. This left a multibillion dollar legitimate market that Purdue could expand into by taking market share from competitors for appropriate patients. For example, management advised the Board in the 2012 "Opioid Market Overview" presentation that Purdue faced competition in just the ERO market from Avinza, Exalgo, Embeda, Duragesic, Kadian, Nucynta ER, Opana ER, Dolophine ER, and generics.[456] In 2015, management advised the Board that they expected five more competitors to be entering the ERO market: Belbuca (made by Endo), Vantrela ER (Teva), ALO-02 (Pfizer), Xtampza ER (Collegium), and MorphaBond ER (Inspirion).[457]

309. The Board thus was advised that Purdue's opioids medications were serving a portion of a much larger opioid market, which new competitors continued to enter.

310. *Second*, in the same November 2012 "Opioid Market Overview," management advised the Board—in advance of its retention of McKinsey—that it planned to use as a key marketing point in the future the anticipated approval by the FDA of a new label recognizing ADF OxyContin's abuse-deterrent properties.

311. The goal, as articulated by management, was to encourage HCPs to prescribe OxyContin over competitors' prescription opioids that did not have abuse-deterrent properties.[458]

312. Emphasizing OxyContin's abuse-deterrent properties in marketing is not a

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[456] JX-2342 (10/25/12 Email Attaching 2013 Sales & Mktg. Presentation to Board) (PPLPC012000396109) at slide 2.

[457] JX-2425 (11/30/15 2016 Budget Presentation) (PPLPC063000003207) at -253.

[458] *See, e.g.*, JX-2342 (10/25/12 Email Attaching Sales & Mktg. Presentation to Board) (PPLPC012000396109) at slide 13 (listing Opportunities for Purdue's Sales and Marketing: "New formulation is favorably impacting abuse"); *id.* at 25 (identifying "Tamper-Resistant Formulation" as an opportunity for OxyContin).

marketing approach designed to cultivate the diversion market.

313. The FDA approved a new label recognizing ADF OxyContin's abuse-deterrent properties in April 2013,[459] and management engaged McKinsey the same month.[460]

314. McKinsey subsequently recommended, as management had earlier, that Purdue emphasize OxyContin's abuse-deterrent properties in its marketing.[461]

315. E2E, as implemented, did emphasize OxyContin's abuse-deterrent properties.[462]

316. *Third*, the Board understood that McKinsey's advice and E2E were exclusively aimed at the legitimate market for prescription opioids.

317. The Board was advised that E2E aimed to persuade doctors to select OxyContin over its competitors for appropriate patients, and all of the Purdue marketing material presented to the Board reflected this.[463]

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[459] *See* JX-2349 (FDA Press Release, FDA approves abuse-deterrent labeling for reformulated OxyContin (Apr. 16, 2013) https://web.archive.org/web/20130419012709/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm348252.htm).

[460] *See* JX-2347 (4/10/13 Email from R. Gasdia) (PPLPC012000417566); JX-2350 (5/19/13 Email from D. Rosen) (PPLPC012000424137).

[461] *See, e.g.*, JX-2075 (July 25, 2013 Board Agenda) (PPLP004409781) at -882 ("We detected a consistent difference between pain specialists and PCPs in their understanding of the new formulation and AD [abuse-deterrent] label change. Many pain specialists saw significant value in the AD properties while PCPs generally had a lower level of understanding and a correspondingly lower level of perceived value. Pain specialists suggested PCP perception of AD value was largely driven by their incorrect assessment of the lack of abuse risk in their patients. In our initial rep rides, we have seen missed opportunities for medical follow up to improve physician understanding")).

[462] *See* JX-2361 (9/12/13 Presentation to Board) (PPLPC063000002005) at -009; JX-2418 (Nov. 2014 Budget Proposal for 2015) (PPLP004411368) at -408; JX-2377 (Nov. 2013 Budget Proposal for 2014) (PPLP004409973).

[463] *See* JX-2096 (Sackler Addendum A) at ¶113 (citing JX-2377 (Nov. 2013 Budget Proposal for 2014) (PPLP004409973) at -10059)); *see also* JX-2353 (2013 Individualize the Dose brochure) (PAZ000046439) at -442, -446, -448 ; JX-2343 (2012 Conversion and Titration Guide)

318. The Board was informed that 68% of immediate-release ("**IR**") oxycodone conversions went to competing extended-release opioids and that Purdue was targeting this market, emphasizing OxyContin's abuse-deterrent properties in its marketing.[464]

319. The Board had no reason to understand that an HCP who prescribed ADF OxyContin rather than another prescription opioid—after being detailed by a Purdue sales representative—was writing a prescription that was not for legitimate medical purposes.

320. A prescriber who changed a patient's prescription from an IR opioid to ADF OxyContin was making abuse by crushing or snorting more difficult.

321. A prescriber who changed a patient's prescription from a generic opioid to branded OxyContin was increasing the cost of the patient's opioid prescription, a financial hindrance to abuse.

322. *Fourth*, the Board understood that compliance was built into the E2E program. A November 2013 presentation to the Board showed that E2E would be overseen by an Executive Oversight Team that included Purdue's General Counsel and Chief Compliance Officer.[465]

323. *Fifth*, some Claimants suggested that McKinsey's recommendation to market to high-decile prescribers was suspect or improper.

(PAK000971874) at -879, -881, -883, -884, -885, -891; JX-1989 (8/28/20 David Sackler Deposition Tr.) at 338:17–339:16.

[464] JX-2418 (Nov. 2014 Budget Proposal for 2015) (PPLP004411368) at -408, -409, -412, -413.

[465] *See* JX-2377 (Nov. 2013 Budget Proposal for 2014) (PPLP004409973) at -10022. *See also* JX-2386 (12/17/13 Presentation to E2E Executive Oversight Team) (PPLPC014000232245) at slides 24–25, 35–40 (Presentation to E2E Executive Oversight Team (confirming "Compliance monitoring activities" built into program).

324. However, E2E was aimed at persuading prescribers to switch appropriate patients from Purdue's competitors' products to Purdue opioids.[466]

325. There is nothing suspect about the fact that high-decile HCPs prescribed more OxyContin than low-decile prescribers since medical practitioners in specialties that involve patients with significant pain prescribe more opioids than HCPs who see fewer such patients.[467]

326. There is nothing improper about using commercially-available past prescribing information to identify prescribers who treat pain patients.[468]

327. *Sixth*, notes from an October 2013 Board meeting reflect the Board's comments/questions in regard to the E2E project that Purdue's marketing and salesforce should be driven by a public mission of helping patients and physicians—to "not just push to obtain scripts ... do well by doing good."[469] The Board further commented:

> In terms of incentives, the salesforce (and indeed the entire organization) should <u>be</u> driven to be of high value to patients and physicians (and the healthcare system), and not simply to increase prescriptions for Purdue products.

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[466] *See, e.g.*, JX-2418 (Nov. 2014 Budget Proposal for 2015) (PPLP004411368) at -409 (Purdue seeking to convert IR prescriptions to OxyContin prescriptions); *id.* at –413 (Purdue seeking to convert appropriate patients on "IR oxycodone to OxyContin" and to call on HCPs with a high "oxycodone to non-OxyContin switch rate"); JX-2384 (11/22/13 McKinsey Presentation) (PPLPUCC9008739108) at -157 (McKinsey's presentations included a sample HCP who—after being called on by Purdue sales representatives—went from writing 23% of his ERO prescriptions as OxyContin in one year to 43% the next, with success defined as educating HCPs to consider whether OxyContin was a better option for some patients than the competitor opioids).

[467] *See* JX-2384 (11/22/13 McKinsey Presentation) (PPLPUCC9008739108) at -124 (McKinsey presentation reflecting that some practices—*e.g.*, orthopedists, rheumatologists, oncologists—prescribed more OxyContin than others).

[468] To the contrary, the Supreme Court has held that doing so is protected by the First Amendment, striking down a Vermont law aimed at preventing pharmaceutical companies from using commercially available prescribing information to tailor their message to prescribers. *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 578–79 (2011).

[469] JX-2376 (11/1/13 email re "Board Notes & Actions") (PPLPC012000449535).

JX-2382 (11/18/13 email re Budget Meeting Notes & Actions) (PPLPC012000452389) at -392.

328. *Seventh*, McKinsey is widely recognized as "a leading management consulting firm,"[470] and the Former Directors were statutorily entitled to rely on such expertise.[471]

329. *Eighth*, McKinsey repeatedly informed the Board that its advice was simply to implement "industry best practices" at Purdue.[472] No evidence has been adduced that the Former Directors had any reason to question that advice.

2. Communications with Former Directors

330. Claimants assert that identified communications demonstrate that the Former Directors directed Purdue's marketing.

331. None of the identified communications involve the late Beverly Sackler.

332. None of the remaining communications reflect that any Former Director approved or directed deceptive marketing during the Relevant Period

a. Richard Sackler Did Not Control or Participate in Purdue's Marketing During the Relevant Period

333. No evidence has been adduced that, during the Relevant Period, Richard Sackler

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[470] *Mindspirit, LLC v. Evalueserve Ltd.*, 470 F. Supp. 3d 366, 370 (S.D.N.Y. 2020); *see also, e.g.*, *Samaritan Inns v. District of Columbia*, 1995 WL 405710 (D.D.C. June 30, 1995) ("an internationally respected consulting firm"); *Mercier v. Inter-Tel (Del.), Inc*., 929 A.2d 786, 799 (Del. Ch. 2007) ("the respected firm of McKinsey & Co").

[471] N.Y. BUS. CORP. LAW §717(a)(2) ("… a director shall be entitled to rely on information … presented by ... persons as to matters which the director believes to be within such person's professional or expert competence").

[472] *See, e.g.*, JX-2354 (8/8/13 McKinsey Report) (PPLP004409890) at -892; *see also* JX-2075 (July 2013 Report from McKinsey) (PPLP004409781) at -877, -879, -887("These ideas are primarily about implementing industry best practices in execution. These best practices can be adapted for Purdue and rolled out quickly.… Industry best practice targets physicians based on a composite value.... Best practice field force optimization requires a significant holistic approach....").

controlled or participated in decisions about what Purdue's marketing would say, usurped the role of marketing executives, or engaged in conduct outside the proper province of a director.

334. Documents cited by Claimants show Richard Sackler requesting information from management about sales and marketing and about the performance of Butrans, whose launch did not meet management's forecast.

335. For example, the some Claimants allege that Richard Sackler "demand[ed] more details about sales and marketing."[473]

- The cited email was sent in 2010,[474] and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2010.[475]

- The email asks management to "[p]lease circulate to the interested Board members a package of presentations" for Butrans that describe "(1) The marketing program, (2) The sales program, (3) The phase 4 research program, (4) The 2nd gen patch program, [and] (5) The pro forma for the product through 2015."[476]

- The information that Purdue management provided in response was the Butrans Commercial Strategy Plan Board Presentation, dated July 22, 2010. In it, management did not seek Board approval of any marketing statements and assured the Board that Purdue would provide prescribers "[a]ppropriate fair balance information … including contraindications, warnings, precautions and safety information," and would "[p]roperly educate healthcare professionals on … [t]he full prescribing information and appropriate use of Butrans."[477]

336. Some Claimants allege that Richard Sackler "demand[ed] a briefing on how the sales visits were going in the field" for Butrans.[478]

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[473] MA AG FAC ¶304. *See also* CA AG FAC ¶¶201, 216; DE AG ¶¶115-16, 17 (at pp. 44, 208).

[474] JX-2304 (5/3/11 Email from John Stewart) (PPLPC042000023301).

[475] *See* ¶127, *supra*.

[476] JX-2287 (7/1/10 Email from Richard Sackler) (PPLPC012000277480).

[477] JX-2289 (7/22/10 Butrans Commercial Strategy Plan Board Presentation) (PPLPC018000404193) at slides 20, 46.

[478] MA AG FAC ¶328. *See also* CA AG FAC ¶211; VT AG Compl. ¶219; CT AG SAC ¶144.

- The cited email was sent in 2011,[479] and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2011.[480]

- In the cited email Richard Sackler makes this request: "I'd like a briefing on the field experience and intelligence regarding Butrans."[481] There is nothing inappropriate about a director requesting such a briefing.

337. Some Claimants allege that the Former Directors "berated sales managers, [and] the managers turned around and fired straight at reps in the field."[482]

- The cited email was sent in February of 2012,[483] and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement for this period.[484]

- The cited email shows only that Richard Sackler responded to an email from Purdue management informing him that the market share for Butrans increased only slightly, by saying: "This is bad."[485]

338. Some Claimants allege that the Former Directors' "micromanagement was so intrusive that staff begged for relief."[486]

- The cited email was sent in February 2012,[487] and the OIG of HHS has confirmed Purdue's compliance with it Corporate Integrity Agreement for this period.[488]

- The email concerns Richard Sackler's request for adjustments to the data presented in management's "Butrans Weekly Report."

- In the email, members of Purdue's management expressed annoyance at Richard

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479 JX-2298 (1/30/11 email from Richard Sackler) (PPLPC021000352205) at -206.

480 *See* ¶127, *supra*.

481 JX-2298 (1/30/11 email from Richard Sackler) (PPLPC021000352205) at -206.

482 MA AG FAC ¶198. *See also* VT AG Compl. ¶108.

483 JX-2330 (2/7/12 email from Richard Sackler) (PPLPC012000368430).

484 *See* ¶127, *supra*.

485 JX-2330 (2/7/12 email from Richard Sackler) (PPLPC012000368430).

486 MA AG FAC ¶¶197, 373. *See also* VT AG Compl. ¶108; CA AG FAC ¶¶9, 208, 223].

487 JX-2331 (3/8/12 Email from Russell Gasdia) (PPLPC012000368569).

488 *See* ¶127, *supra*.

Sackler's requests "for data," but also recognized that "he has a right to know and is highly analytical." It does not mention micromanagement.[489]

- Richard Sackler has testified, with respect to Purdue staff complaints about his requests, "They find me a pain in the ***, yes."[490]

339. Some Claimants contend that "Richard argued to the Vice President of Sales that a legally required warning about Purdue's opioids wasn't needed."[491]

- The cited email exchange occurred in 2011, [492] and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2011.[493]
- In the email, which concerns Butrans, Richard Sackler specifically told Purdue management that "the issue isn't whether [Purdue] can promote" Butrans for post-operative use, but rather why the particular information was not on a different section of the FDA-approved label.[494]
- Richard Sackler was told that others in the organization shared his concern, but that the FDA rejected the proposal. *Id.* That ended the matter.

340. Some Claimants allege that Richard Sackler "pushed staff to sell more of the highest doses of opioids and get more pills in each prescription."[495]

- The cited email was sent in 2008,[496] and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2008.[497]
- The email shows that Richard Sackler provided comments on a presentation slides that were intended to help improve sales—*e.g.*, "as a means to reach for the

[489] JX-2331 (3/8/12 Email from Russell Gasdia) (PPLPC012000368569).

[490] JX-1985 (3/7/19 Richard Sackler MDL Dep. Tr.) at 157:15–18 (adding: "Sorry for the vulgarity").

[491] MA AG FAC ¶356. *See also* VT AG Compl. ¶243; DE AG Compl. ¶161; MD AG SOC ¶260.

[492] JX-2312 (7/20/11 Emails with Richard Sackler) (PPLPC001000091100).

[493] *See* ¶127, *supra*.

[494] JX-2312 (7/20/11 Emails with Richard Sackler) (PPLPC001000091100).

[495] MA AG FAC ¶232. *See also* VT AG ¶141.

[496] JX-2252 (3/8/08 Email from Richard Sackler) (PPLPC012000175155).

[497] *See* ¶127, *supra*.

increasing trajectory of Rx's."[498] In the comments, Richard Sackler suggested that prescriptions be reported to the Board "on an adjusted or KG basis."

- The email says nothing about promoting higher doses or getting more pills in each prescription.

341. Some Claimants allege that "Richard Sackler sent Sales VP Russell Gasdia a series of questions about Purdue's efforts to get patients to take higher doses and stay on opioids for longer times."[499]

- The cited email was sent in 2008,[500] and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2008.[501]
- The email asks about insurance limitations on the number of tablets covered and says nothing about promotion of higher doses.[502]

342. Some Claimants allege that "Richard Sackler told staff that he was not satisfied with OxyContin sales and demanded a plan to 'boost' them."[503]

- This email was sent in 2009,[504] and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2009.[505]
- In the cited email, Richard Sackler asked Purdue management to "[p]lease add to the US Board meeting" various items, one of which a "[p]rogram to boost OxyContin tablets." *Id.*
- In an Executive Committee Meeting two months earlier, Purdue management had informed the PPI Board that OxyContin sales fell short of expectations because

[498] JX-2252 (3/8/08 Email from Richard Sackler) (PPLPC012000175155) at -157.

[499] MA AG FAC ¶240. *See also* VT AG Compl. ¶138.

[500] JX-2256 (4/22/08 Email from Richard Sackler) (PPLPC012000179497).

[501] *See* ¶127, *supra*.

[502] JX-2256 (4/22/08 Email from Richard Sackler) (PPLPC012000179497) ("What is the status of covered lives now with OxyContin?").

[503] MA AG FAC ¶260. *See also* VT AG Compl. ¶167; DE AG Compl. ¶132.

[504] JX-2271 (7/20/09 Email from Richard Sackler) (PPLPC012000232015) at -016.

[505] *See* ¶127, *supra*.

"Mallinckrodt … shipped its supply of generic OxyContin more rapidly than projected."[506] In the cited email, Richard Sackler was requesting more information about an issue facing Purdue: the replacement of Purdue's market share by generic competition.

343. Some Claimants allege that Richard Sackler "insisted that sales rep push the doctors who prescribed the most drugs."[507]

- The cited email was sent in 2011,[508] and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement for 2011.[509]
- The email was a reply to an email from the head of sales advising that "[t]he managers all felt that we can improve in our call focus and frequency on high-potential prescribers."[510]
- Richard Sackler asked why "we are calling on non-high potential prescribers," *id.*, and does not contain a demand "to push doctors who prescribed the most drugs."

344. Some Claimants allege that Richard Sackler "demand[ed] information about Purdue's opioid savings cards … to make sure he understood the sales tactic down to the smallest detail."[511]

- The cited email was sent in 2008,[512] and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2008.[513]
- In the email, Richard Sackler asks questions about a savings card analysis provided by management because the analysis contained a typo that made it

[506] JX-2269 (5/20/09 Executive Committee Meeting) (PPLPC041000008788).

[507] MA AG FAC ¶353. *See also* VT AG Compl. ¶240.

[508] JX-2308 (6/16/11 Email from Richard Sackler) (PPLPC012000329706).

[509] ¶127, *supra*; JX-1839 (Fourth OIG Certification) (PPLP004428603); JX-2705 (2Q 2011 Board Report) (PPLP004366913) at -940.

[510] JX-2308 (6/16/11 Email from Richard Sackler) (PPLPC012000329706).

[511] MA AG FAC ¶219. *See also* VT AG Compl. ¶129; DE AG Compl. ¶115.

[512] JX-2251 (1/30/08 Email from Richard Sackler) (PPLPC012000168321) ("My fault. It was a typo. It is 50 not 500.… Sorry for the confusion.").

[513] *See* ¶127, *supra*.

incomprehensible. *Id.*

345. Some Claimants allege that Richard Sackler "directed staff to send him weekly reports on OxyContin."[514]

- The cited email was sent in 2009,[515] and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2009.[516]

- In the email, Richard Sackler asks only for sales information: "Please add me to the weekly circulation."[517]

346. Some Claimants allege that "Richard Sackler met with sales reps for several days at the Butrans Launch Meeting and discussed how they would promote Purdue's newest opioid."[518]

- The cited email concerns an event that took place in 2011,[519] and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2011.[520]

- The email shows that Richard Sackler attended the first few days of the Butrans Launch Meeting.[521]

- No evidence has been adduced that there was any discussion of the content of marketing material for Butrans.

347. Some Claimants allege that Richard Sackler "went into the field to promote

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514 MA AG FAC ¶266. *See also* DE AG Compl. ¶135; VT AG Compl. ¶174.

515 JX-2279 (10/8/09 Email from Richard Sackler) (PPLPC012000241515).

516 *See* ¶127, *supra*

517 JX-2279 (10/8/09 Email from Richard Sackler) (PPLPC012000241515).

518 MA AG FAC ¶328. *See also* VA AG Compl. ¶219; CA AG FAC ¶211; MD AG SOC ¶257.

519 JX-2299 (1/31/11 Email from Russell Gasdia) (PPLPC012000308393).

520 *See* ¶127, *supra*

521 JX-2299 (1/31/11 Email from Russell Gasdia) (PPLPC012000308393).

opioids to doctors alongside a sales rep."[522]

- This ride-along occurred in 2011,[523] and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2011.[524]
- No evidence has been adduced that Richard Sackler promoted or marketed any Purdue product on this ride-along.
- The cited documents show that Richard Sackler rode along with one sales representative for one day to get "a better idea of the prospects" for Butrans.[525]
- The evidence establishes that, in consultation with the VP of compliance, Richard Sackler's role was "mum and … anonymous."[526]

348. Although, as Richard's late brother Jonathan complained, Richard sometimes "bombard[ed] execs with his ideas,"[527] no evidence has been adduced showing that Richard Sackler was making any decisions about what Purdue's marketing should say during the Relevant Period.

349. **Pre-2007 Evidence.** In the absence of any evidence that Richard Sackler participated in Purdue's marketing during the Relevant Period, Claimants cite decades-old documents from the late 1990s and early 2000s as supposed evidence of Richard Sacklers' his involvement. These stale documents all concern conduct that was released by Purdue's 2007 Settlements, are beyond all applicable limitations periods and are otherwise irrelevant.

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[522] MA AG FAC ¶356, *see also* NY AG FAC ¶¶393, 196;CA AG FAC ¶210; VT AG Compl. ¶¶107, 243.

[523] JX-2304 (5/3/11 Email from John Stewart) (PPLPC042000023301).

[524] *See* ¶127, *supra*.

[525] JX-2304 (5/3/11 Email from John Stewart) (PPLPC042000023301).

[526] JX-2307 (6/16/11 Email from Bert Weinstein) (PPLPC012000329722).

[527] JX-2423 (6/20/15 Email from Theresa Sackler) (PPLPUCC9004448656) at -656.

b. Jonathan Sackler Did Not Control or Participate in Purdue's Marketing During the Relevant Period

350. No evidence has been adduced that Jonathan Sackler participated in the drafting or approval of any of Purdue's marketing materials or otherwise personally participated in marketing.

351. Documents cited by Claimants consist of requests by Jonathan Sackler for sales and market share information that have no bearing on the substance of any marketing materials. Many of the documents concern Butrans, and many were sent during the period that the OIG of HHS was confirming PPLP's compliance with the CIA (7/31/07-7/30/12):

- A January 2012 email from Jonathan Sackler to Russell Gasdia (Vice President of Sales), with the subject line "Butrans" asking: "Russ, are you going to resume a weekly (bi-weekly?) update on sales?"[528]
- Notes from a 2011 Board meeting which reflect that Jonathan Sackler "asked for market share change over time for opioid medicines over time --- by strength."[529]
- A May 25, 2011 email from Jonathan Sackler replying to a report from Purdue's CEO addressing Butrans' lackluster launch: "[T]his is starting to look ugly. Let's talk."[530]
- A 2015 request by Jonathan Sackler for a "briefing on OxyContin market impact of CDC guidelines"[531]—guidelines which Purdue distributed to more than 150,000 health care providers.[532]

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[528] JX-2327 (1/9/12 Email from Jonathan Sackler) (PPLPC012000358983); *see* MA AG FAC ¶366; VT AG Compl. ¶252; CT AG SAC ¶144; DE AG Compl. ¶165.

[529] JX-2311 (6/28/11 Notes from Board Meeting) (PPLPC012000331345); *see* MA AG FAC ¶358; CA AG FAC ¶206; DE AG Compl. ¶160; CT AG SAC ¶144.

[530] JX-2306 (5/25/11 Email from Jonathan Sackler) (PPLPC012000326192); at -194; *see* MA AG FAC ¶344. *See also* VT AG Compl. ¶231; DE AG Compl. ¶158.

[531] JX-2429 (12/10/15 Executive Committee Presentation) (PPLPC011000073230) at slide 13; *see* MA AG FAC ¶468. *See also* VT AG Compl. ¶347; DE AG Compl. ¶17.

[532] JX-2467 (2019 Purdue Pharma Statement) (MSF00638656) at -657 (email forwarding a Purdue press release stating: "In 2016, the Centers for Disease Control (CDC) issued a new

352. Claimants point to an April 2008 email from Jonathan Sackler to Dr. Robert Kaiko, a Purdue employee, in which he wrote: "I was thinking about the differences between pain patients and drug abusers in their reaction to opioids. Has anybody tried using PET to explore this?"[533]

- There is no evidence that anyone at Purdue conducted this research, and it is irrelevant to any claim in these cases.
- This email was sent in 2008, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2008.

353. Claimants contend that a March 2008 email showed that "Jonathan, Kathe, and Mortimer Sackler were also pushing staff about sales" because Purdue's staff "told those three Sacklers that they would use opioid savings cards to meet the challenge of keeping OxyContin scripts at the same level in 2008 as in 2007."[534]

- Jonathan Sackler was copied on but sent none of the cited emails, which discuss the impact of the savings card on Purdue's budget and forecast and say nothing about the contents of Purdue's marketing.[535]
- This email chain was sent in 2008, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2008.

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guideline for prescribing opioids for chronic pain (CDC Guidelines). Purdue immediately emailed the guidelines to over 150,000 healthcare professionals throughout the country and subsequently distributed thousands of CDC 'tear sheets' setting forth the guideline's recommendations including to doctors in Massachusetts."); JX-1998 (Lisa Miller Dep. Tr. at 203:17–19, *State of Oklahoma ex rel. Mike Hunter v. Purdue Pharma L.P.*, No. CJ-2017-816 (Dist. Ct. Cleveland Cnty. Aug. 29, 2018)) ("As far as the CDC, we distributed the CDC to a number of health care professionals through email and link shortly after it came out.").

533 JX-1699 (4/30/08 Email from Jonathan Sackler) (PWG004455200). See NYAG FAC ¶374; First Amended Complaint, *State of Minnesota v. Purdue Pharma L.P.*, Case No. 27-CV-18-10788 (Minn. Dist. Ct., Hennepin Cnty. July 8, 2019) ("**MN AG FAC**"), ¶245.

534 *See* MA AG FAC ¶234. *See also* VT AG Compl. ¶143; DE AG Compl. ¶120.

535 JX-2252 (8/3/16 Email from Edward Mahony) (PPLPC012000175155).

354. Claimants allege that Jonathan Sackler served on Rhodes' governance committee and business development committee (*see, e.g.*, NYAG FAC ¶402), but he never served as a Rhodes director or on any Rhodes committee.[536] Further, Rhodes was a manufacturer of generic opioids and did not engage in any marketing.[537]

c. David Sackler Did Not Control or Participate in Purdue's Marketing During the Relevant Period

355. No evidence has been adduced that David Sackler participated in the drafting or approval of any of Purdue's marketing materials or otherwise personally participated in marketing.

356. David Sackler was never an officer or executive of Purdue, and he did not join the Board until July 2012.[538]

357. At his deposition in these bankruptcy cases, no documents were offered to show that David Sackler participated in decisions about the contents of Purdue's marketing, and he testified that management gave the Board periodic presentations about Purdue's marketing, and the Board did not give "a lot of feedback" in return. JX-1989 (8/28/20 David Sackler Dep. Tr.) at 245:6-17.

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[536] *See* JX-2091 (Rhodes Pharmaceuticals Inc. Directors List) (RhodesAG-000000064); JX-2092 (Rhodes Technologies Inc. Directors List) (RhodesAG-000000065).

[537] Debtors' Information Brief at 9–11 ("Rhodes Pharma does not have – and never has had – sales representatives promote or market its opioid drugs to prescribers or patients;" "In May 2019, Rhodes Pharma and Rhodes Tech were contributed to Purdue Pharma, becoming subsidiaries of Purdue.").

[538] JX-2090 (Purdue Directors List) (PPLPUCC500140094); JX-2093 (Purdue's Responses and Objections to Plaintiff's First Set of Interrogatories, *People of the State of New York v. Purdue Pharma L.P., et al.*, No. 400016/2018 (N.Y. Sup. Ct., Suffolk Cnty. Dec. 20, 2018) at 15–33 (listing all Purdue officers during relevant period).

358. Claimants allege, that David Sackler served on the governance committee and business development committee of Rhodes' board (*see* NYAG FAC ¶402), but he never served as a Rhodes director or on any Rhodes committee.[539] Further, Rhodes was a manufacturer of generic opioids and did not engage in any marketing.[540]

359. Claimants allege that David Sackler received in 2014 a memorandum from his grandfather, Raymond Sackler, that "specifically" concerned "putting patients on high doses of opioids for long periods of time."[541]

- The memo was a history of Purdue's "Activities Relating … to Acceptance of Abuse Deterrent Formulations of Opioids." JX-2408 (5/4/14 Memo from Burt Rosen and Alan Must) (PWG000412143).
- It explained the results of the 2012 PROP petition, including the FDA's denial of maximum daily dose and maximum duration limitations, and FDA's agreement to modify the label for "moderate to severe pain" to "the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." *Id*.

VII. PURDUE'S POST-2007 MARKETING

360. Purdue's marketing during the Relevant Period was aimed at persuading prescribers to choose Purdue's opioids over competing analgesics when medically appropriate for the patient.[542]

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539 *See* JX-2091 (Rhodes Pharmaceuticals Inc. Board of Directors) (RhodesAG-000000064); JX-2092 (Rhodes Technologies Inc. Board of Directors) (RhodesAG-000000065).

540 Debtors' Information Brief at 9–11 ("Rhodes Pharma does not have – and never has had – sales representatives promote or market its opioid drugs to prescribers or patients;" "In May 2019, Rhodes Pharma and Rhodes Tech were contributed to Purdue Pharma, becoming subsidiaries of Purdue.").

541 *See* MA AG FAC ¶440. *See also* CA AG FAC ¶196; VT AG Compl. ¶318.

542 *See, e.g.*, JX-2353 (2013 Individualize the Dose Brochure) (PAZ000046439) at -442, -446; JX-2343 (2012 Conversion and Titration Guide) (PAK000971874) at -879, -881, -883–885; JX-2010 (11/24/20 Craig Landau Dep. Tr.) at 176:16–25.

361. No evidence has been adduced that Purdue's post-2007 marketing increased the total number of prescription opioids in use. The evidence shows that Purdue's sales declined.[543]

362. Non-Estate Claimants contend that Purdue's post-2007 marketing was deceptive primarily in 12 ways (the "**Marketing Claims**").[544] Plaintiffs have not established by a preponderance of the evidence that any of the 12 challenged representations was false.

A. Purdue Disclosed—and HCPs Were Aware—That OxyContin Is Addictive

363. OxyContin is a Schedule II controlled substance and is so labeled.

- Schedule II controlled substances are "drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are considered dangerous."[545]
- OxyContin can lawfully be bought only with a prescription from a licensed physician registered with the DEA.[546]
- Licensed physicians are highly trained professionals who learn about the addictive

[543] *See* JX-2465 (1/7/18 Purdue Written Reponses to 30(b)(6) Topics) (POK003735973), at -984–985 (showing that OxyContin sales as measured in dollars were less in 2014, 2015, 2016 and 2017 than in 2008).

[544] Because the POC fails to specify the alleged misstatements that Claimants challenge, the alleged misstatements identified here are the ones enumerated in the First Amended Complaint (at pp. 32–45) filed in the NYAG FAC, the MA AG OC, and the MA AG FAC, and copied in countless complaints thereafter. To the extent any Claimants purport to assert that other pieces of Purdue's marketing or statements made by Purdue sales personnel, none of which are identified in the POC, were deceptive, the Objector reserves the right to address any such additional bases for their respective claims in subsequent briefing and after full discovery.

[545] *See* DEA, DRUG SCHEDULING, https://www.dea.gov/drug-scheduling (last visited on Mar. 20, 2021). *See also* 21 U.S.C. §812(b)(2) (setting forth the requirements for a drug to be placed on Schedule II: "(A) The drug or other substance has a high potential for abuse. (B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. (C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.").

[546] *See* 21 C.F.R. §1306.03(a)(2) ("A prescription for a controlled substance may be issued only by an individual practitioner who is … registered … [under] this chapter," subject to limited exemptions); 21 C.F.R. §1306.06 ("A prescription for a controlled substance may only be filled by a pharmacist … either registered individually or employed in a registered pharmacy…").

properties of opioids at medical school and know that Schedule II drugs have a risk of abuse and addiction.

- In case after case, physicians have testified that they are aware of the risks of Schedule II narcotics such as OxyContin, the risk that such drugs may be abused or lead to addiction, and that they therefore take the prospect of prescribing a Schedule II narcotic to a patient very seriously.[547]

364. OxyContin's label has always disclosed the risk of abuse and addiction. Its original 1995 label stated: "OxyContin is a mu-agonist opioid with an abuse liability similar to morphine and is a Schedule II controlled substance. Oxycodone products are common targets for both drug abusers and drug addicts."[548] The 1995 label warned that "abuse of opioids can occur in the absence of true psychological dependence and is characterized by misuse for non-medical purposes, often in combination with other psychoactive substances."[549] It also cautioned that "care should be taken to prevent diversion or abuse by proper handling."[550]

[547] *See, e.g.*, *Bodie v. Purdue Pharma Co.*, 236 F. App'x 511, 520 (11th Cir. 2007) (summarizing treating physician's testimony regarding his awareness of the risks of addiction to OxyContin and other Schedule II narcotics); *Timmons v. Purdue Pharma Co.*, 2006 WL 263602, at *44 (M.D. Fla. Feb. 2, 2006) ("all four physicians testified that they were independently aware of the risks of addiction to OxyContin"); *Cornelius v. Cain*, 2004 WL 48102, at *4 (Fla. Cir. Ct. Jan. 5, 2004) (record demonstrated that the "physicians had received training and were aware of the abuse potential associated with prescribing narcotic medications like OxyContin"); *Koenig v. Purdue Pharma Co.*, 435 F. Supp. 2d 551, 555 (N.D. Tex. 2006) (prescribing physician "was aware of the addictive risks associated with OxyContin").

[548] *See* JX-2097 (1995 Label) (PPLPC044000064536) at -537.

[549] *Id*.

[550] *Id*.

365. In 2001, Purdue added a black box warning to the OxyContin label:

> WARNING:
>
> OxyContin® is an opioid agonist and a Schedule II controlled substance **with an abuse liability similar to morphine**.
>
> **Oxycodone can be abused in a manner similar to other opioid agonists, legal or illicit**. This should be considered when prescribing or dispensing OxyContin in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

JX-2103 (2001 Label) (PDD1501070063) at -063. Per the FDA: "A boxed warning is the most serious warning placed in the labeling of a prescription medication."[551]

366. The 2001 label also added additional information in and updated the DRUG ABUSE AND ADDICTION section to reflect:

- "Oxycodone, like morphine and other opioids used in analgesia, can be abused and is subject to criminal diversion."[552]
- "Drug addiction is characterized by compulsive use, use for non-medical purposes, and continued use despite harm or risk of harm. Drug addiction is a treatable disease, utilizing a multi-disciplinary approach, but relapse is common."[553]
- "'Drug-seeking' behavior is very common in addicts and drug abusers. Drug-seeking tactics include emergency calls or visits near the end of office hours, refusal to undergo appropriate examination, testing or referral, repeated 'loss' of prescriptions, tampering with prescriptions and reluctance to provide prior medical records or contact information for other treating physician(s). 'Doctor shopping' to obtain additional prescriptions is common among drug abusers and people suffering from untreated addiction."[554]
- "Physicians should be aware that addiction may not be accompanied by concurrent tolerance and symptoms of physical dependence in all addicts. In addition, abuse of opioids can occur in the absence of true addiction and is characterized by misuse

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551 JX-2182 (9/9/08 FDA Letter to Connecticut Attorney General) at 2 (rejecting request by Connecticut Attorney General to add to the warnings on OxyContin's label).

552 JX-2103 (2001 Label) (PDD1501070063) at -069, -076.

553 *Id.* at -069.

554 *Id.*

for non-medical purposes, often in combination with other psychoactive substances. OxyContin, like other opioids, has been diverted for non-medical use."[555]

- "Proper assessment of the patient, proper prescribing practices, periodic re-evaluation of therapy, and proper dispensing and storage are appropriate measures that help to limit abuse of opioid drugs."[556]

367. In 2001, Purdue sent a letter to prescribers to alert them to the 2001 label changes and the reasons that prompted them:

[redacted]

[redacted].[557]

368. Every subsequent version of the OxyContin label repeated these warnings, including in a prominent black box warning.[558]

B. Alleged Misrepresentation: The Risk of Addiction From Chronic Opioid Therapy Is Low

369. Claimants' contend that Purdue's marketing was misleading because it claimed

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[555] *Id.* at -069-070.

[556] *Id.* at -070.

[557] *See* JX-2220 (7/18/01 Purdue Dear HCP Letter) (PDD1715240425) at -425.

[558] *See, e.g.*, JX-2107 (Nov. 2010 Label) at 5, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022272s006lbl.pdf; JX-2113 (2014 Label) at 1, 17–18, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022272s022lbl.pdf; JX-2117 (2016 Label) at 1, 27, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022272s034lbl.pdf; JX-2120 (2018 Label) at 1, 27–18, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022272s039lbl.pdf.

that the risk of addiction from chronic opioid therapy is low.[559]

370. No evidence has been elicited showing that Purdue made this representation during the Relevant Period, and Claimants themselves made this representation prior to the Relevant Period.[560]

371. No evidence has been elicited that this representation is false. The FDA website affirms its truth today,[561] as do independent studies.[562]

372. No evidence has been elicited that any HCP was misled by this alleged misrepresentation. The CDC explained that it issued its 2016 Guideline for Prescribing Opioids

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[559] *See, e.g.*, NYAG FAC at 32.

[560] *See, e.g.*, N.Y. DEP'T OF HEALTH, WHEN DEATH IS SOUGHT: ASSISTED SUICIDE AND EUTHANASIA IN THE MEDICAL CONTEXT, ch. 3, *available at* https://www.health.ny.gov/regulations/task_force/reports_publications/when_death_is_sought/chap3.htm ("Psychological dependence is extremely rare in patients receiving opioids.... [T]he rate of psychological dependence in patients treated with narcotic drugs for pain is less than one percent."); JX-2177 (STATE OF NEW YORK PUBLIC HEALTH COUNCIL, BREAKING DOWN THE BARRIERS TO EFFECTIVE PAIN MANAGEMENT: RECOMMENDATION TO IMPROVE THE ASSESSMENT AND TREATMENT OF PAIN IN NEW YORK STATE at 23 (Feb. 13, 1998)) ("Unfortunately, the public does not understand that opioid addiction when treating bona fide pain is rare.").

[561] FDA, A GUIDE TO SAFE USE OF PAIN MEDICINE, https://www.fda.gov/consumers/consumer-updates/guide-safe-use-pain-medicine ("According to the National Institutes of Health, studies have shown that properly managed medical use of opioid analgesic compounds (taken exactly as prescribed) is safe, can manage pain effectively, and rarely causes addiction.").

[562] *See, e.g.*, Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain--Misconceptions and Mitigation Strategies*, 384 NEW ENG. J. MED.1253, 1256 (2016), *available at* https://www.nejm.org/doi/pdf/10.1056/NEJMra1507771?articleTools=true ("Addiction occurs in only a small percentage of persons who are exposed to opioids—even among those with preexisting vulnerabilities"); Benjamin W. Friedman, *et al*., *Opioid Use During the Six Months After an Emergency Department Visit for Acute Pain: A Prospective Cohort Study*, ANNALS OF EMERGENCY MED. (Nov. 1, 2019), https://www.annemergmed.com/article/S0196-0644(19)31134-5/pdf (484-patient study finding only 1% of patients visiting the emergency room between November 2017 and August 2018 with no opioid use in the prior 6 months who were prescribed opioids on discharge developed persistent opioid use indicating addiction).

for Chronic Pain *because* primary care HCPs were aware of and concerned about the risk of addiction from prescription opioids and wanted guidance.[563]

C. <u>Alleged Misrepresentation: The Concept of "Pseudoaddiction"</u>

373. Claimants assert that Purdue's use of the concept pseudoaddiction is misleading.[564]

374. Pseudoaddiction describes a condition in which a patient exhibits behaviors reflecting a preoccupation with achieving adequate pain relief (drug-seeking behavior) because s/he has unrelieved pain, not because s/he is psychologically dependent on opioids.

375. The federal government has repeatedly recognized the concept of pseudoaddiction.

- It is used in the FDA-approved label for Percodan.[565]
- It is used in the FDA-approved label for Percocet.[566]
- The U.S. Department of Veteran Affairs and Department of Defense use it in a

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[563] *See* Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 CDC MORBIDITY AND MORTALITY WEEKLY REPORT at 2 (Mar. 18, 2016) https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf ("Primary care clinicians … express concern about patient addiction…. Across specialties, physicians believe … that addiction is a common consequence of prolonged use, and that long-term opioid therapy often is overprescribed for patients with chronic noncancer pain.").

[564] *See, e.g.*, NYAG FAC at 34; MA AG FAC ¶¶77–83; MD AG SOC ¶26; RI AG SAC ¶88; CA AG FAC 103.

[565] JX-2285 (Percodan Label 2010) at 17, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/007337s046lbl.pdf ("Pseudoaddiction refers to pain relief seeking behavior of patients whose pain is poorly managed.").

[566] JX-2228 (Percocet Label 2006) at 2, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/040330s015,040341s013,040434s003lbl.pdf ("Pseudoaddiction refers to pain relief seeking behavior of patients whose pain is poorly managed").

clinical practice guideline for the management of patients with chronic pain.[567]

376. The FDA-approved label for OxyContin does not use the term but describes the condition: "Preoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control."[568]

377. The 27 Consent Judgment States—which include 15 Non-Consenting States[569]—approved Purdue's use of educational materials that discussed pseudoaddiction at length and distinguished it from addiction.

- Paragraph 15 of the Consent Judgments required that Purdue provide to all HCPs it contacted written educational material focused on detecting and preventing abuse and diversion.[570]
- On August 6, 2007, Purdue sent a copy of this educational material—a 27-page brochure entitled *Providing Relief, Preventing Abuse*—to all 27 Consent Judgment AGs to ensure their satisfaction with Purdue's compliance with ¶15.[571]

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[567] DEP'T OF VETERANS AFFAIRS & DEP'T OF DEFENSE, CLINICAL PRACTICE GUIDELINE FOR MANAGEMENT OF OPIOID THERAPY FOR CHRONIC PAIN 13 (May 2010), *available at* https://www.va.gov/painmanagement/docs/cpg_opioidtherapy_summary.pdf ("Pseudoaddiction describes patient behaviors that may occur when pain is undertreated.... Misunderstanding of this phenomenon may lead the clinician to inappropriately stigmatize the patient with the label 'addict.'").

[568] *See* JX-2097 (1995 Label) (PPLPC044000064536) at -537 ("Preoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control."); JX-2120 (2018 Label) at 28, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022272s039lbl.pdf, ("Preoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control.").

[569] California, Connecticut, the District of Columbia, Idaho, Illinois, Maine, Maryland, Massachusetts, Nevada, Oregon, Pennsylvania, Vermont, Virginia, Washington, and Wisconsin.

[570] Ky. Consent Judgment at ¶15 (obligating Purdue to "provide to each [HCP] … written, non-branded educational information related to detecting and preventing abuse and diversion of opioid analgesics ... for ten (10) years following the Effective Date of this Judgment").

[571] JX-2242 (8/6/07 Letter from Purdue to Ohio Attorney General, with certification and attachment) (PPLPUCC004238887).

- The brochure described pseudoaddiction in detail.[572]

- Every State acquiesced in Purdue's providing this educational material concerning pseudoaddiction to every HCP Purdue contacted for the next ten years, per ¶15.

D. Alleged Misrepresentation: The Risk of Addiction Can Easily Be Identified and Managed

378. Claimants maintain that Purdue's marketing falsely claimed that the risk that patients would become addicted could be easily identified and managed.[573]

379. No evidence has been elicited showing that any marketing materials by Purdue ever made that claim.

- The NYAG FAC identifies two publications distributed by Purdue as containing this misrepresentation: the American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (PPLP004114870) (JX-2477) and the *Pain Management Kit* from Partners Against Pain (PKY183145184) (JX-2219) (*see* NYAG FAC ¶318).

- Neither of these publications makes that claim.

380. Claimants alleged that opioid risk assessment tools referenced in these materials were deceptive because the tools are not perfect and might have misled prescribers into believing that the risk of addiction could be mitigated more easily than it can in reality (*see* NYAG FAC ¶318).

381. Many of the tools that Claimants fault Purdue for were developed by the federal government as a form of prescriber education to combat the opioid crisis.

- Partners Against Pain's *Pain Management Kit* referred to certain questionnaires and checklists, described as "Drug Abuse Screening Tools." *See* JX-2219 (PKY183145184) at -232–237. These included the Screening Techniques from HHS's Center for Substance Abuse Prevention (*id*. at -235).

- The HHS screening tools also referenced the CAGE and CAGE-AID

[572] *Id*. at -897.

[573] *See* NYAG FAC, at p. 36 and ¶¶126–28, 317–18.

Questionnaires (*id*. at -236).

- The federal Substance Abuse and Mental Health Services Administration ("**SAMHSA**") and federal Health Resources and Services Administration also endorse the CAGE and CAGE-AID Questionnaires. *See* http://web.archive.org/web/20200317024834/https://www.integration.samhsa.gov/clinical-practice/screening-tools.

382. The Consent Judgment States approved Purdue's recommendation of the CAGE Questionnaire in the education materials Purdue distributed pursuant to ¶15 of the Consent Judgments.[574]

383. Tools of this type are still recommended by the FDA.

- The FDA Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain advises physicians to use, "[w]hen appropriate, evidence-based, standardized scales and tools ... to document pain characteristics and guide management decisions throughout treatment."[575]

E. Alleged Misrepresentation: Opioid Withdrawal Can Be Avoided With Tapering

384. Claimants contend that Purdue's marketing deceptively claimed that opioid withdrawal can be avoided with tapering,[576] and that references to tapering are deceptive because tapering is not necessarily an "effective way to help those who have developed an opiate use disorder overcome the physical consequences of withdrawal." NYAG FAC ¶129.

385. No evidence has been elicited that Purdue ever claimed that tapering is an effective way to help those with opiate use disorder.

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[574] JX-2242 (8/6/07 Letter from Purdue to Ohio Attorney General, with certification and attachment) (PPLPUCC004238887) at -901.

[575] FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain 3 (2018), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Opioid_analgesic_2018_09_18_FDA_Blueprint.pdf.

[576] *See* NYAG FAC at p. 37; CO AG FAC ¶349.

386. The Colorado Attorney General cites a 2010 Purdue marketing pamphlet, *A Training Guide for Healthcare Providers*,[577] but the pamphlet states quite clearly that "Patients With Physical Dependence Who Do Not Have an Addiction Disorder ... [c]an generally discontinue their medicine with mild to no withdrawal syndrome once their symptoms are gone by gradually tapering the dosage according to their doctor's orders." *See* JX-2281 (2010 *A Training Guide for Healthcare Providers* Pamphlet) (PTN000000596) at -603.

387. No evidence has been elicited establishing that it is deceptive about referring to the use of tapering. The FDA-approved labels for OxyContin instruct physicians that tapering is an appropriate means of discontinuing the medication.[578]

F. Alleged Misrepresentation: Opioid Doses Can Be Increased Without Limits or Greater Risks

388. Claimants contend that Purdue marketing deceptively indicated that HCPs "could safely increase patients' opioid doses without risk in order to achieve pain relief." NYAG FAC ¶130.[579]

389. No evidence has been elicited showing that Purdue's marketing said that doses can be increased without risk.

- The FDA-approved label for OxyContin explicitly identifies risks associated with dosage increases, including life-threatening respiratory depression.[580]

390. The New York Attorney General points to two statements in Purdue's marketing

[577] CO AG FAC ¶350 (citing JX-2281 (2010 *A Training Guide for Healthcare Providers* Pamphlet) (PTN000000596)).

[578] *See, e.g.*, JX-2097 (1995 Label) (PPLPC044000064536) at -537; JX-2114 (2013 Label) (PPLPC003000060503) at -514; JX-2120 (2018 Label) at 10, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022272s039lbl.pdf.

[579] *See also, e.g.*, MA AG FAC ¶¶67–76; CT AG SAC ¶¶47-55.

[580] *See, e.g.*, JX-2120 (2018 Label) at §§5.3, 17, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022272s039lbl.pdf.

materials—(1) that prescribers should titrate in order to find the right dose, and (2) that OxyContin has no ceiling dose (NYAG FAC ¶¶296, 321–22).

391. Both of those statements are FDA-approved, and neither implies that opioid doses can be increased without risk.

392. There is nothing deceptive about referring to titration—it is a well-established technique by which HCPs determine the appropriate dose of a medicine.

- OxyContin's FDA-approved label instructs physicians to: "Individually titrate OxyContin to a dose that provides adequate analgesia and minimizes adverse reactions." *See, e.g.*, JX-2114 (2013 Label) (PPLPC003000060503) at -509.

- The 2016 CDC Opioid Guidelines contemplate that physicians will use titration to determine the appropriate dose. *See, e.g.*, 2016 CDC Opioid Guidelines (Recommendation No. 5 addressing titration strategies), *available at* https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

- The FDA Briefing Book for its June 11-12, 2019 Joint Meeting of the Drug Safety and Risk Management Advisory Committee and Anesthetic and Analgesic Drug Products Advisory Committee states that: "The general approach is to initiate opioid treatment with a low dose and individually titrate to a tolerable dose that provides adequate analgesia".[581]

- Purdue's marketing materials recommended a conservative initial OxyContin dose—just half the patient's estimated daily oxycodone requirement—and then "tailor[ing] the dose ... titrating up or down," as clinical need dictates.[582]

393. It was not deceptive for Purdue to reference the scientific fact that OxyContin—like oxycodone generally—has no ceiling dose, as its FDA-approved label has always stated. *E.g.*:

- The 1995 FDA-approved label for OxyContin stated: "Like all pure opioid agonists, there is no ceiling effect to analgesia, such as is seen with partial agonists

[581] JX-2193 (6/11/19 FDA Briefing Document) at 14, *available at* https://www.fda.gov/media/127780/download.

[582] *See, e.g.*, JX-2353 (2013 Individualize the Dose Brochure) (PAZ000046439) at -446, -448; JX-2343 (2012 Conversion and Titration Guide) (PAK000971874) at -883–885, 891.

or non-opioid analgesics." JX-2097 (1995 Label) (PPLPC044000064536) at -536.

- The 2016 label stated: "Like all full opioid agonists, there is no ceiling effect to analgesia for oxycodone."[583]

- The 2018 label stated: "Like all full opioid agonists, there is no ceiling effect to analgesia for oxycodone."[584]

394. The FDA has repeatedly reaffirmed that there is no ceiling or maximum dose for prescription opioids:

- In 2008, the FDA wrote: "Opioids, including oxycodone, have no dose ceiling based on a plateau for efficacy.... Therefore, there is no maximum dose for opioids." JX-2182 (9/9/08 FDA Letter) at 7.

- In 2012, Physicians for Responsible Opioid Prescribing petitioned the FDA to "[a]dd a maximum daily dose, equivalent to 100 milligrams of morphine for non-cancer pain ... [because] three large observational studies published in 2010 and 2011 found dose-related overdose risk in patients on chronic opioid therapy." *See* JX-2359 (9/10/13 FDA Response to PROP Letter) (PPLPC019000835061) at -061, -072. The FDA rejected that application because "the scientific literature does not support establishing a maximum recommended daily dose of 100 mg MED." *Id.* at -072.

- In a 2020 letter to Senator Maggie Hassan, the FDA reaffirmed this determination: "[T]he data do not suggest a threshold [dose] below which opioid use is 'safe' and above which it is 'too risky.'"[585]

G. <u>Alleged Misrepresentation: Long Term Opioid Use Improves Functioning</u>

395. Claimants maintain that Purdue's marketing deceptively claimed that long-term opioid use improved people's lives.

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[583] JX-2117 (2016 Label) at 33, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022272s034lbl.pdf.

[584] JX-2120 (2018 Label) at §12.1, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022272s039lbl.pdf.

[585] JX-2473 (1/21/20 Letter from Janet Woodcock, Director for FDA, to Senator Maggie Hassan) at 13, *available at* https://www.hassan.senate.gov/imo/media/doc/FDA%20RESPONSE%20HASSAN%201.21.20.pdf.

396. The evidence establishes that Purdue's internal procedures expressly prohibited such quality of life claims.

- Purdue's internal guidelines for promotional materials specifically stated that Purdue promotional materials could not make quality of life claims.[586]

- Purdue also had policies in place to prevent its sales force from making such claims. Its Standard Operating Procedure for sales personnel said: [redacted][587]

397. The evidence establishes that Purdue's Compliance Department monitored and disciplined quality of life claims.[588]

398. Claimants have relied on just one post-2007 call note that referred to quality of life. *See* NYAG FAC ¶301 (citing 2008 call note).[589]

- The apparent source of this is a document containing the records of over 498,000 call notes made by Purdue's representatives documenting sales calls in New York from 2006 to 2017. JX-2482 (PNY000000074).

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[586] *See* JX-2333 (4/20/12 Product Promotional Guidelines) (PPLP003517436) at -448 ("The following topics are specifically excluded from promotional materials at this time. … Quality of Life (QoL) claims (e.g., improvements in functionality or sleep), including visual representations or pictorials that are not substantiated by patient reported outcomes (PROs) validated tools."). *See also, e.g.*, JX-2364 (9/16/13 OxyContin Product Promotional Guideline) (PPLP003517710) at -726 (similar); JX-2416 (8/29/14 OxyContin Product Promotional Guideline) (PPLP003517763) at -780 (similar); JX-2438 (9/20/16 OxyContin Product Promotional Guideline) (PPLP003517380) at -397 (similar).

[587] *See* JX-1880 (2/27/12 SOP for Analgesic Sales Force) (PPLPC014000164042) at -055.

[588] *See, e.g.*, JX-2693 (1Q 2013 Board Report) (PPLP004367540) at -591 ("As a result of monitoring and rapid completion of current field sales call notes, we look to address compliance issues before they develop into serious concerns; e.g., ... quality of life and implied superiority claims...."); *see also, e.g.*, JX-2280 (10/28/09 Sales and Marketing Compliance Committee Agenda) (PPLP004436174) at -175.

[589] NYAG FAC ¶301 also cites some 2006 call notes. As addressed above, New York and other entities released all claims about pre-2007 marketing.

- That single post-2007 quality of life violation occurred in 2008, and the OIG of HHS confirmed Purdue's compliance with the Corporate Integrity Agreement in 2008.

- No evidence has been adduced that this single post-2007 quality of life violation led to issuance of even a single prescription or caused any damage to any Claimant.

399. Claimants also suggest that Purdue should have told HCPs that OxyContin should not be used for long-term treatment.

- OxyContin is only approved for long-term use, as the FDA-approved label states.[590]

- The FDA has repeatedly reiterated its conclusion that OxyContin can properly be prescribed for long-term use. In 2020, the FDA stated: "Chronic or long-term use (in appropriate situations), with no maximum duration, was always part of the approved use of OxyContin."[591]

H. Alleged Misrepresentation: Alternative Forms of Pain Relief Pose Greater Risks than Opioids

400. Claimants assert that Purdue misled prescribers by stating or implying that opioids were superior to other forms of pain relief because those other forms of pain relief posed risks.[592]

401. The evidence establishes Purdue prohibited comparative claims.

402. As articulated in a Purdue training manual:

[590] *See* JX-2120 (2018 Label) at 1, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022272s039lbl.pdf ("OxyContin is an opioid agonist indicated for the management of pain severe enough to require ... long-term opioid treatment....") (capitalization omitted).

[591] JX-2473 (1/21/20 Letter from Janet Woodcock, Director for FDA, to Senator Maggie Hassan) at 4, *available at* https://www.hassan.senate.gov/imo/media/doc/FDA%20RESPONSE%20HASSAN%201.21.20.pdf.

[592] *See, e.g.*, NYAG FAC at 38.

- "Statements cannot represent or suggest that a drug is safer/more effective (or make any other sort of comparative claim) unless there is substantial evidence/clinical trials supporting the statement—We have no drugs that satisfy this standard."
- "Be careful not to IMPLY superiority in your discussions with HCPs."
- "What If It Is the HCP Who Is Making These Statements? ... When this happens, what should you do? ... There are circumstances where it is necessary to respond to the HCP's statement (e.g., when failure to do so might leave a misimpression about our products."[593]

403. The evidence establishes that Purdue's Compliance Department took steps—including training and discipline—to ensure that sales representatives did not make or repeat comparative claims.[594]

I. <u>**Alleged Misrepresentation: OxyContin Provides 12 Hours of Pain Relief**</u>

404. Claimants contend that Purdue's marketing was deceptive because it promoted

[593] JX-2316 (Oct. 2011 Guidelines on Product Promotion: Comparative Claims Workshop) (PPLP003439475) at -486–87, 490. *See also* JX-2333 (4/20/12 Product Promotional Guidelines) (PPLP003517436) at -439 ("Care should be taken to avoid any comparative claims to other products or classes of drugs."); *id.* at -448 ("5.0 TOPICS PRECLUDED FROM PROMOTION": "Comparative efficacy or safety claims") JX-2364 (9/16/13 OxyContin Product Promotional Guideline) (PPLP003517710) at -726 (similar); JX-2416 (8/29/14 OxyContin Product Promotional Guideline) (PPLP003517763) at -779 (similar); JX-2438 (9/20/16 OxyContin Product Promotional Guideline) (PPLP003517380) at -397 (similar).

[594] *See* JX-2058 (3Q 2010 Board Report) (PPLP004366991) at -7004 ("A routine review of call notes revealed references that suggested potential comparative claims of superiority of Purdue products relative to competitors. ... Follow up discipline included: termination of one representative for multiple compliance violations, probation for a second representative, and written warning letters for an additional 16 representatives."); *see also, e.g.*, JX-2663 (2Q 2010 Quarterly Compliance Report) (PPLP004404551) at -564 ("open sales investigations into representative call notes concerning potential improper promotion—comparative claims … superiority claims"); JX-2664 (3Q 2010 Quarterly Compliance Report) (PPLP004405460) at -490 (investigation into "potential comparative claims"); JX-2674 (1Q 2013 Quarterly Compliance Report) (PPLP004409694) at -696 (measures in place to prevent sales representatives making "superiority claims"); JX-2693 (1Q 2013 Board Report) (PPLP004367540) at -591 (the Company is "look[ing] to address compliance issues before they develop into serious concerns; e.g., … quality of life and implied superiority claims").

OxyContin for 12-hour use.[595]

405. The evidence establishes that Purdue is required—by federal law (*see* 21 C.F.R. §201.100(d)(1)) and the 2007 Consent Judgments (¶3)—to market OxyContin for 12-hour use because the FDA approved OxyContin for 12-hour dosing only.[596]

406. Purdue is prohibited from marketing OxyContin for less than 12-hour use because to do so would constitute promoting an off-label use of the medication.

407. The FDA rejected a request to alter OxyContin's 12-hour dosing.[597]

J. Alleged Misrepresentation: OxyContin's 2010 Reformulation Is Abuse Deterrent

408. Claimants argue that Purdue's marketing was deceptive because it referred to the "abuse-deterrent formulation" (ADF) of OxyContin.[598]

409. The evidence does not support the claim that there was any deception.

- The FDA has determined that ADF OxyContin has abuse-deterrent properties, announcing in 2013: "The FDA has determined that the reformulated product has abuse-deterrent properties."[599]

- In 2013, the FDA approved a revision to OxyContin's label reflecting its

[595] *See, e.g.*, NYAG FAC ¶¶146–50, 303–08.

[596] *See, e.g.*, JX-2107 (Nov. 2010 Label) at 5, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022272s006lbl.pdf ("Individually titrate OxyContin to a dose that provides adequate analgesia and minimizes adverse reactions while maintaining an every-twelve-hour dosing regimen."); JX-2120 (2018 Label) at 6, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022272s039lbl.pdf ("OXYCONTIN is administered orally every 12 hours.").

[597] JX-2182 (9/9/08 FDA Letter to Connecticut Attorney General) at 16.

[598] *See, e.g.*, NYAG FAC p. 44.

[599] JX-2349 (4/16/13 FDA Press Release, *FDA approves abuse-deterrent labeling for reformulated OxyContin*), *available at* https://web.archive.org/web/20130419012709/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm348252.htm.

abuse-deterrent properties, stating that ADF OxyContin was "formulated with inactive ingredients intended to make the tablet more difficult to manipulate for misuse and abuse." [600] At the same time, the label makes clear that the reformulation did not deter all abuse.[601]

- The FDA continues to endorse the use and development of abuse-deterrent opioids, while continuing to recognize that they are not abuse-proof.[602]

410. Law enforcement agencies have also praised the development of ADF opioids, including ADF OxyContin:

- The head of the DEA's Office of Diversion Control speaking to the National Association of Attorneys General in 2013 said: "[T]he new OxyContin delivery system ... is indeed very difficult—it's almost impossible to crush. It's very difficult to extract the drug from the delivery system. And Purdue did do us a major favor because the old product was very easy to circumvent." He added that he believed that, if ADF were adopted by other manufacturers, the country "would see a decrease … in the amount of overdoses." He summed up: "[M]y hat's off to Purdue for doing that because they did see their issue and they did make a change in that delivery system which was very good."[603]

- Forty-two Attorneys General—including 7 of the 9 objecting States—wrote to the FDA, urging it to promote the development of ADF opioids: "Ensuring that generic opioids, like their branded counterparts, have abuse-deterrent properties is a commonsense improvement that provides yet another important tool in the fight against our nation's prescription drug epidemic."[604]

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[600] JX-2114 (2013 Label) (PPLPC003000060503) at -522–525.

[601] *See id.* at -522.

[602] *Abuse Deterrent Opioid Analgesics*, FDA, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/abuse-deterrent-opioid-analgesics (updated Feb. 1, 2021) ("The FDA is encouraging the development of prescription opioids with abuse-deterrent formulations (ADFs) to help combat the opioid crisis. The agency recognizes that abuse deterrent opioids are not abuse- or addiction-proof but are a step toward products that may help reduce abuse").

[603] JX-2365 (9/17/13 Transcript of Presidential Initiative Current Issues In Drug Abuse Panel) (PPLPC018000884102).

[604] JX-2385 (12/16/13 Letter from AGs to FDA) (PPLPC046000057423) (the signatory Non-Consenting States: Colorado, Delaware, Hawaii, Idaho, Illinois, Iowa, Maine, Maryland, Massachusetts, Minnesota, Nevada, New Hampshire, New Jersey, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, and Wisconsin).

- In a letter to the FDA, the Governor of Connecticut, a Non-Consenting State, praised Purdue's ADF and urged the FDA to encourage other manufacturers to develop abuse-deterrent formulations.[605]

K. Alleged Misrepresentation: Purdue Worked Diligently to Detect and Prevent Diversion of Opioids

411. Claimants contend that Purdue's marketing was deceptive on the theory that Purdue advertised its "efforts to monitor and report abuse and diversion of [its] products" and that this message was "designed to create a false sense of security." NYAG FAC ¶154.

412. No evidence has been adduced that any Purdue marketing discussed Purdue's diversion programs, and the record reflects that Purdue undertook extensive anti-diversion initiatives at substantial expense.[606]

L. Alleged Misrepresentation: Savings Cards Deceptively Kept Patients on Opioids Longer

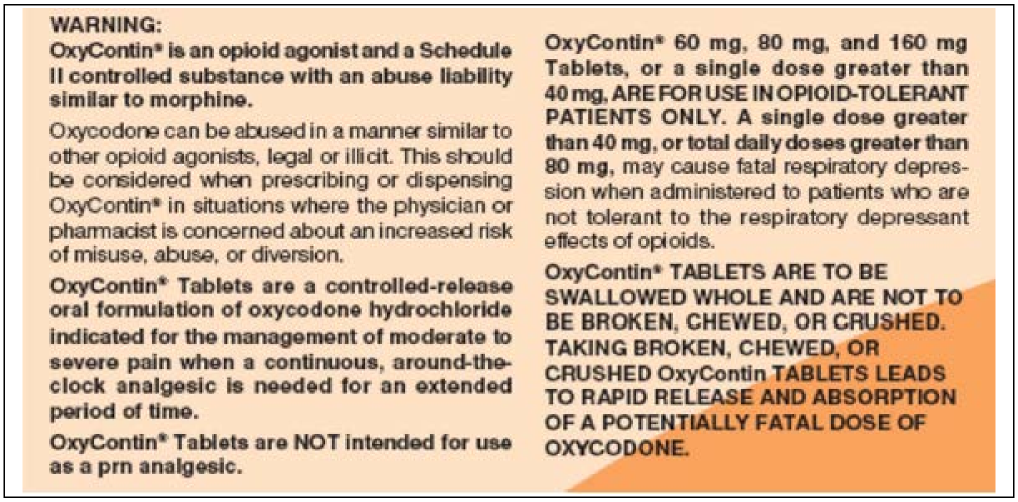
413. Claimants assert that Purdue's savings cards deceptively kept patients on opioids for longer.[607]

414. The evidence establishes that Purdue's savings cards did not contain any false claims about Purdue's opioids—they included the FDA-approved black boxed warnings about the risk associated with OxyContin.

[605] JX-2345 (Feb. 27, 2013 Letter to FDA) (PPLPC020000776814).

[606] *See* Debtors' Informational Brief at 31–32; *see also Select Initiatives to Address Opioid Crisis*, Purdue, https://www.purduepharma.com/addressing-the-crisis/select-initiatives/ (last visited July 29, 2021).

[607] MA AG FAC ¶420. *See also* VT AG Compl. ¶269; DE AG Compl. ¶171.



WARNING:
OxyContin® is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine.

Oxycodone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OxyContin® in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

OxyContin® Tablets are a controlled-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

OxyContin® Tablets are NOT intended for use as a prn analgesic.

OxyContin® 60 mg, 80 mg, and 160 mg Tablets, or a single dose greater than 40 mg, ARE FOR USE IN OPIOID-TOLERANT PATIENTS ONLY. A single dose greater than 40 mg, or total daily doses greater than 80 mg, may cause fatal respiratory depression when administered to patients who are not tolerant to the respiratory depressant effects of opioids.

OxyContin® TABLETS ARE TO BE SWALLOWED WHOLE AND ARE NOT TO BE BROKEN, CHEWED, OR CRUSHED. TAKING BROKEN, CHEWED, OR CRUSHED OxyContin TABLETS LEADS TO RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF OXYCODONE.

JX-2275 (2009 Savings Card) (PPLPC012000235543) at slide 14.

VIII. THE CHALLENGED DISTRIBUTIONS

A. Cash Distributions

415. From 2008 to 2017, PPLP and Rhodes Pharmaceuticals L.P. and affiliates ("**Rhodes**") made total net cash distributions ("**Distributions**") of $10.4 billion to or for the benefit of Sackler Family Members.[608]

416. Of this, $10.318 billion consisted of Distributions from PPLP and $28.495 million consisted of Distributions from Rhodes (*id.*).

417. The $10.318 billion in PPLP Distributions comprise the following:

(1) $4.213 billion in "**US Partner Distributions**"—transfers to Sackler entities and, ultimately, trusts for the benefit of Sackler Family Members. These stopped in 2016, except for one distribution of $198,544 made in 2017 (*id.* at Slide 25).

(2) $1.547 billion in "**Ex-US Distributions**" invested in or for the benefit of IACs. The last of these was made in 2016 (*id.*). No Side B family member

[608] JX-1902 (AlixPartners Cash Transfer Report, *In re Purdue Pharma L.P.*, Case No. 19-23649-rdd (Bankr. S.D.N.Y. Dec. 16, 2019) (ECF No. 654-1)) ("**AlixPartners Cash Transfer Report**") at slides 11, 25.

or trust was a transferee of any Ex-US Distribution.

(3) $4.559 billion in "**Tax Distributions**" paid to taxing authorities or to Sackler entities to pay taxes arising from PPLP's business activities (*id.*).

418. Half of the Distributions were transferred to or for the benefit of Side A, and half to or for the benefit of Side B.[609]

419. Distributions occurred regularly, in the ordinary course of business, after formal approval by PPI's Board of Directors.[610]

420. The fact that Purdue distributed profits to the Sackler Family was not concealed.[611]

421. The federal, state and governmental Claimants received approximately 90% of the Tax Distributions in the form of tax payments.[612]

[609] JX-1902 (AlixPartners Cash Transfer Report) at slides 25, 64-71, 339; *see also* JX-2464 (Summary of PPLP Distributions prepared by Purdue) (PPLPUCC9011830859) ("**PPLP Distributions Summary**") at "2008 Detail" through "2017 Detail" Tabs.

[610] *See, e.g.*, JX-2017 (April 18, 2008 PPI Board decision) (PPLP004416690); JX-2021 (March 5, 2009 PPI Board decision) (PPLP004416824); JX-2028 (December 2, 2010 PPI Board decision) (PPLP004417123); JX-2030 (April 6, 2011 PPI Board decision) (PPLP004417148); JX-2035 (April 2, 2012 PPI Board decision) (PPLP004417227).

[611] *Forbes* reported in 2015 that the "Sackler family's net worth" is based in part on "accumulated dividends" and totaled "a conservative $14 billion." Alex Morrell, *The OxyContin Clan: The $14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families*, FORBES (Jul. 1, 2015), available at https://www.forbes.com/sites/ alexmorrell/2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/. *See also* David Armstrong, *The man at the center of the secret OxyContin files*, STAT (May 12, 2016), available at https://www.statnews.com/2016/05/12/man-center-secret-oxycontin-files/ ("All of the company's profits—totaling billions of dollars alone from OxyContin—go to Sackler family trusts and entities.").

[612] *See, e.g.*, JX-2464 (PPLP Distributions Summary) (PPLPUCC9011830859) at "2017 Detail" Tab (reflecting Tax Distributions paid to state and federal taking authorities); *id*. at "2015 Detail" Tab; JX-1902 (AlixPartners Cash Transfer Report) at slides 27, 67-71, 73.

B. Non-Cash Transfers

422. During the period from January 1, 2008, to September 15, 2019, PPLP made non-cash transfers to Sackler Family Members and entities.[613]

423. The Debtors contend that certain non-cash transfers were made, collectively, for $1.4 billion less than reasonably equivalent value.[614] The analysis on which this contention rests has been challenged as methodologically unsound, speculative and inconsistent with the facts.[615]

424. The Court need not resolve this contested issue of fact because, for the reasons set forth below, it concludes, among other things, that PPLP was not insolvent when the Distributions were made; that PPLP received fair consideration for the Tax Distributions; and that neither PPLP nor the Former Directors believed or intended that the Distributions would cause Purdue to incur debts beyond its ability to pay as the debts matured.

IX. PURDUE WAS SOLVENT WHEN THE DISTRIBUTIONS WERE MADE IN 2008-2016

425. During the period from 2008 through 2016, Purdue was solvent and adequately capitalized, and it was not rendered insolvent or inadequately capitalized by any of the Distributions.[616]

426. Purdue was solvent under the Balance Sheet Test because, using the highest reasonable estimate of Purdue's liabilities, the positive difference between its assets and its

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[613] *See generally* JX-1903 (AlixPartners Non-Cash Transfers Analysis, *In re Purdue Pharma L.P.*, Case No. 19-23649-rdd (Bankr. S.D.N.Y. May 29, 2020) (ECF No. 1194-1)).

[614] *See* JX-0521 (Expert Report of David W. Deramus).

[615] *See* JX-0509 (Rebuttal Report of Philip Green).

[616] *See generally* JX-1937 (Expert Report of Maureen Chakraborty, Ph.D.) ("**Chakraborty Rept.**") ¶¶11-18.

liabilities was never less than $1.3 billion and was as much as $9.2 billion.[617]

427. Purdue was solvent under the Cash Flow Test because, using the highest reasonable estimate of Purdue's liabilities, its reasonably expected cash flows were sufficient to meet its reasonably expected liabilities as and when they would come due over a multi-year period.[618]

428. Purdue was solvent under the Capital Adequacy Test because, using the highest reasonable estimate of Purdue's liabilities, it had an adequate amount of capital to sustain its operations under a stress-test scenario.[619]

429. Purdue had no funded debt.[620]

430. Purdue did not face threatening opioid litigation before 2017. Purdue faced none of the suits that ultimately precipitated its bankruptcy filing until 2014, when 2 were filed, and only 3 more followed in 2015-16.[621]

431. Contemporaneous Purdue documents, including projections, 10-year plans and other submissions to the Board, demonstrate that Purdue did not reasonably foresee a substantial threat from opioid—or any other—litigation from 2008 through 2016.[622]

432. Contemporaneous Purdue documents establish that, as late as 2016, Purdue management believed—and advised the Board—that its litigation exposure was low and

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[617] *Id.* ¶¶13-15, 158-163.

[618] *Id.* ¶¶16, 164-170.

[619] *Id*. ¶¶17, 171-180.

[620] *Id.* ¶178; *see also* Debtors' Informational Brief at 1.

[621] ¶¶437-442, *infra*.

[622] ¶¶458-472, *infra*.

declining.[623]

433. Almost 63% of all PPLP Distributions ($6,484,430,150 of $10,318,183,895) were made from January 1, 2008 through July 31, 2012, while the federal monitor was in place and was confirming that PPLP was operating in compliance with the CIA, which was designed to promote compliance with federal healthcare law.[624]

434. JPMorgan, Moody's and S&P all evaluated Purdue in 2014-2016 and concluded it was stable and highly creditworthy. None identified a risk that Purdue could be subject to new opioid litigations.[625]

435. Other opioid manufacturers, which have been sued alongside Purdue for causing the opioid crisis, were not viewed by market participants as being insolvent based on the possibility of future litigation and judgments. They continued to access the capital markets and repeatedly raised debt financing throughout the period when Distributions were made, and credit rating agencies' ratings reflect that they did not perceive substantial risk for these companies until after the Distributions ceased.[626]

436. The ultimate number and scale of the Pending Opioid Actions, and any potential liabilities associated with those actions, were not reasonably foreseeable during the period from 2008 through 2016.[627]

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[623] ¶472, *infra*.

[624] JX-1977 (Chakraborty Rept. Appendix H, Tab 1) (column D, row 1638 [$10,318,183,895] minus column D, row 828 [$3,833,753,745] = $6,484,430,150).

[625] ¶¶533-537, *infra*; JX-1937 (Chakraborty Rept.) ¶114-118.

[626] ¶¶539-42, *infra*; JX-1937 (Chakraborty Rept.) ¶¶ 122-145.

[627] JX-1937 (Chakraborty Rept.) ¶¶13, 88-154.

A. There Was No Meaningful Litigation When Distributions Were Made

437. None of the thousands of Pending Opioid Actions that precipitated Debtors' bankruptcy filing[628] was filed until 2014, when the first two cases were commenced.[629] One more was filed in 2015;[630] two in 2016;[631] and those filings increased dramatically when 344 cases were filed in 2017.[632]

438. Prior to 2017, Purdue settled governmental claims and investigations for manageable amounts. PPLP settled an investigation by the New York Attorney General with a payment of $75,000 in 2015.[633] PPLP settled a longstanding litigation brought by the Attorney General of Kentucky in 2015 for $24 million paid over 8 years.[634] The amount of this settlement was inflated because PPLP had been judicially determined to have admitted liability by failing to respond to requests for admission.[635] Even this inflated amount, if multiplied by 50 states, was substantially less than a single year's net sales revenue for Purdue for any year between 2008-

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[628] Debtors' Informational Brief at 37.

[629] *People of the State of California v. Purdue et al.*, Case No. 30-2014-00725287-CU-BT-CXC (Cal. Super. Ct., Orange Cnty.) ("**California v. Purdue**"); *City of Chicago v. Purdue Pharma L.P.*, No. 14-cv-04361 (N.D. Ill.) ("**Chicago v. Purdue**").

[630] *State of Mississippi v. Purdue Pharma L.P. et al.*, Case No. G2015-1814 O/3 (Miss. Ch. Ct.) ("**Mississippi v. Purdue**").

[631] *County of Suffolk v. Purdue Pharma L.P., et al.*, Index No. 613760/2016 (N.Y. Sup. Ct., Suffolk Cnty.) ("**County of Suffolk v. Purdue**"); *U.S. ex rel. Robert E. Manchester, et al. v. Purdue Pharma L.P., et al.*, No. 1:16-cv-10947-MLW (D. Mass.) ("**Purdue Qui Tam Action**").

[632] *See* JX-1976 (Chakraborty Rept. App. G) (list of Pending Opioid Actions including filing dates); *id.*, JX-1939 (Chakraborty Rept. Ex. 2).

[633] *See* JX-1889 (Assurance of Discontinuance) (PPLP004035441).

[634] *See* JX-2430 (12/15/15 settlement between Purdue and Kentucky) (PPLPUCC000701839).

[635] *See Purdue Pharma L.P. v. Combs*, 506 S.W.3d 337, 340 (Ky. Ct. App. 2014) (denying Purdue's appeal of order deeming facts admitted).

2016.[636]

439. From 2008-2016, Purdue faced product liability lawsuits, but those actions were never a threat to its solvency. In 2008, management advised the Board that an appropriate reserve for "closing out" all OxyContin litigation would be $200 million.[637] More than a thousand product liability suits had been settled on very manageable terms in 2007.[638] From 2008 through 2019, PPLP paid a total of $342 million in settlements, excluding intellectual property matters.[639] During the same period—between 2008 and 2016—PPLP and its associated companies earned net profits of $10.6 billion.[640]

440. By 2010-11, there were only 24 product liability suits pending against PPLP and

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636 *See* JX-2696 (2008-09 Financial Statements) (PPLPC012000270659) at -663; JX-1843 (2009-10 Financial Statements) (PPLPC012000323951) at -955; JX-1844 (2010-11 Financial Statements) (PPLPMDL0040000537) at -541; JX-1845 (2011-12 Financial Statement) (PPLPC029000544175) at -179; JX-1846 (2012-13 Financial Statement) (PPLPC029000589136) at -140; JX-1847 (2013-14 Financial Statement) (POK003285615) at -620; JX-1848 (2014-15 Financial Statement) (PPLPC011000090527) at -532; JX-1849 (2015-16 Financial Statement) (PPLPC021000890262) at -267.

637 *See, e.g.*, JX-1851 (1/11/08 Board Agenda Book) (PPLP004400663) at -677 ("Possible Reserve for Closing Out OxyContin Litigation = $0.2 billion").

638 *See, e.g.*, JX-2232 (1/27/07 email from Purdue chief legal officer to board members and others re "settlement") (PPLPC044000010048) at -049, -051 (attaching article titled "Purdue settles 90% of pending OxyContin cases;" noting resolution of 1374 individual claims for $75 million, with "several thousand additional claimants ... also settled"). *See also* JX-2442 (11/15/16 email attaching presentation Purdue: Past, Present & Future – Manufacturing and Promoting Opioids Responsibly [excerpts]) (PPLPC002000250048) at slide 7 (stating that "[m]ass tort" claims in "2006-07" were "[r]esolved for ~120M").

639 Disclosure Statement for Fifth Amended Joint Chapter 11 Plan of Reorganization of Purdue Pharma L.P. and its Affiliated Debtors at 166, *In re Purdue Pharma L.P.*, Case No. 19-23649-rdd (Bankr. S.D.N.Y. June 2, 2021) (ECF No. 2983).

640 *See* JX-1937 (Chakraborty Rept.) ¶29, JX-1944 (Chakraborty Rept. Ex. 7) (citing exhibits listed in n. 636, *supra*).

its associated companies, and only 3 of those were being actively litigated.[641] The number of products suits declined after that, and all were dormant by 2014-15.[642]

441. Purdue also won many product liability suits brought by individuals claiming harm from OxyContin.[643] As the United States District Court for the Western District of Virginia observed when it approved the 2007 Federal Settlement, "Courts have consistently found that despite extensive discovery, plaintiffs were unable to show that Purdue's misbranding proximately caused their injuries."[644]

442. Nothing that transpired in the five pre-2017 Pending Opioid Actions before 2017 indicated that Purdue would be subject to an unmanageable increase in litigation starting in 2017:

- *California v. Purdue* was the first of the Pending Opioid Actions filed, commenced in May 2014 by Santa Clara County and the Orange County District Attorney.[645] The Court stayed the case in August 2015 out of deference to the FDA because the suit was "in an area which is best left to agencies such as the FDA who are designed to address such issues." *People v. Pharma*, 2015 WL 5123273, at *2 (Cal. Super. Ct. Aug. 27, 2015). In October 2016, the court lifted that stay "to permit defendants

[641] *See* JX-1844 (2010-11 Financial Statements) (PPLPMDL0040000537) at -574.

[642] *See* JX-1845 (2011-12 Financial Statements) (PPLPC029000544175) at -208 (only 21 product liability cases, of which only 3 were being actively litigated); JX-1847 (2013-14 Financial Statements) (POK003285615) at -655 (only 19 product liability cases, of which only 1 was being actively litigated); JX-1848 (2014-15 Financial Statements) (PPLPC011000090527) at -570 (only 18 product liability cases, all dormant); JX-1849 (2015-16 Financial Statements) (PPLPC021000890262) at -304 (only 19 products cases, all dormant); *see also* JX-1937 (Chakraborty Rept.) ¶98, Figure 5; JX-1952 (Chakraborty Rept. Ex. 15) (citing exhibits listed in n. 636, *supra*).

[643] *See, e.g.*, *Boysaw v. Purdue Pharma*, 2008 WL 4452650 (W.D. Va. Sept. 30, 2008), *aff'd*, 320 F. App'x 178 (4th Cir. 2009) (affirming dismissal OxyContin product liability claim); *Bodie*, 236 F. App'x 511 (same); *Timmons*, 2006 WL 263602 (dismissing OxyContin product liability claims); *Foister v. Purdue Pharma, L.P.*, 295 F. Supp. 2d 693 (E.D. Ky. 2003) (same); *Labzda v. Purdue Pharma, L.P.*, 292 F. Supp. 2d 1346 (S.D. Fla. 2003) (same); *Koenig*, 435 F. Supp. 2d 551 (same); *McCauley*, 331 F. Supp. 2d 449 (same).

[644] *See United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569, 575 (W.D. Va. 2007).

[645] *See* Complaint, *California v. Purdue* (filed May 21, 2014).

to challenge the [Third Amended Complaint]" and to "facilitate early resolution efforts," which the court "strongly encouraged."[646]

- *Chicago v. Purdue* was commenced on June 2, 2014.[647] In May 2015, the court granted in large part Purdue's motion to dismiss.[648] All but two consumer protection claims relating to Purdue's website were dismissed. A September 2016 order granted in part a subsequent motion to dismiss some of the City's remaining claims.[649] After the Third Amended Complaint was filed in October 2016, it was subject to yet another round of dismissal briefing that was not decided until November 2017.[650]

- *Mississippi v. Purdue* was commenced on December 15, 2015, but the Court did not rule on a threshold motion by Defendants to transfer venue until February 2017.[651]

- *County of Suffolk v. Purdue* was filed in August 2016, but the court did not rule on Purdue's motion to dismiss until June 2018.[652]

- The *Purdue Qui Tam Action* was filed under seal in May 2016, ostensibly on behalf of the United States and 29 named states, asserting claims under the applicable false claims actions.[653] In December 2016, after the federal government and all 29 states declined to intervene in the action, the complaint was unsealed.[654] The relator never served the initial complaint on Purdue, and the Amended Complaint was not served until 2018.

[646] *See* Minute Order, *California v. Purdue* (filed October 19, 2016).

[647] *See* Notice of Removal, *Chicago v. Purdue* (June 11, 2014), ECF No. 4.

[648] *See* Memorandum Opinion and Order, *Chicago v. Purdue* (May 8, 2015), ECF No. 288.

[649] *See* Memorandum Opinion and Order, *Chicago v. Purdue* (Sept. 29, 2014), ECF No. 471.

[650] *See* Third Amended Complaint, *Chicago v. Purdue* (Oct. 25, 2016) (Dkt. 478); Minute Entry, *Chicago v. Purdue* (Nov. 16, 2017), ECF No. 659.

[651] *See* Order, *State of Mississippi v. Purdue Pharma L.P. et al*, No. G2015-1814 O/3 (Miss. Ch. Ct. Feb. 13, 2017).

[652] *See* Complaint, *County of Suffolk v. Purdue Pharma L.P., et al.*, Index No. 613760/2016 (N.Y. Sup. Ct. Suffolk Cnty. Aug. 31, 2016), NYSCEF No. 2; Order Denying Motion to Dismiss, *In re Opioid Litigation*, Index No. 400000/2017 (Sup. Ct. Suffolk Cnty. June 18, 2018), NYSCEF 454.

[653] *See* Complaint, *Purdue Qui Tam Action* (May 25, 2016), ECF No. 1.

[654] *See* Notice of United States and Declining States of Election to Decline to Intervene, *Purdue Qui Tam Action* (Nov. 21, 2016), ECF No. 12; *Order*, *Purdue Qui Tam Action* (Dec. 19, 2016), ECF No. 15.

443. None of the Pending Opioid Actions has resulted in a judgment against Purdue.

444. The only Pending Opioid Actions that have been litigated to judgment have been decided in favor of Purdue.[655]

445. *City of New Haven v. Purdue* dismissed the claims against Purdue because, "despite the court begging them for one, the plaintiffs couldn't suggest even a *possible way* to calculate the degree of individual causation in this case."[656] The court in *North Dakota v. Purdue* dismissed the claims against Purdue because (1) "federal law preempts the State's state law claims, which are based on the marketing of Purdue's medication for their FDA-approved uses," and (2) "the State's causal theory is too attenuated."[657]

446. Purdue settled only one of the pre-petition opioid marketing actions—brought by the State of Oklahoma—and, in the settlement agreement, "deni[ed] each and all of the claims and allegations of wrongdoing" and "maintain[ed] that it ha[d] meritorious defenses."[658]

447. Purdue had no judgment creditors when it went into bankruptcy.[659]

448. As the Debtors explained at the outset of these proceedings with respect to the Pending Opioid Actions, "the Debtors believe that these claims are subject to a number of defenses that bar or significantly limit them. But, putting the merits of the litigations aside, the

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[655] *See City of New Haven v. Purdue Pharma L.P.*, 2019 WL 423990 (Conn. Super. Ct. Jan. 8, 2019); Order Granting Motion to Dismiss, *State of North Dakota ex rel. Stenehjem v. Purdue Pharma L.P., et al.*, 2019 WL 2245743 (N.D. Dist. May 10, 2019).

[656] *City of New Haven*, 2019 WL 423990, at *7 (emphasis in original).

[657] *State of North Dakota*, 2019 WL 2245743, at *8, *11.

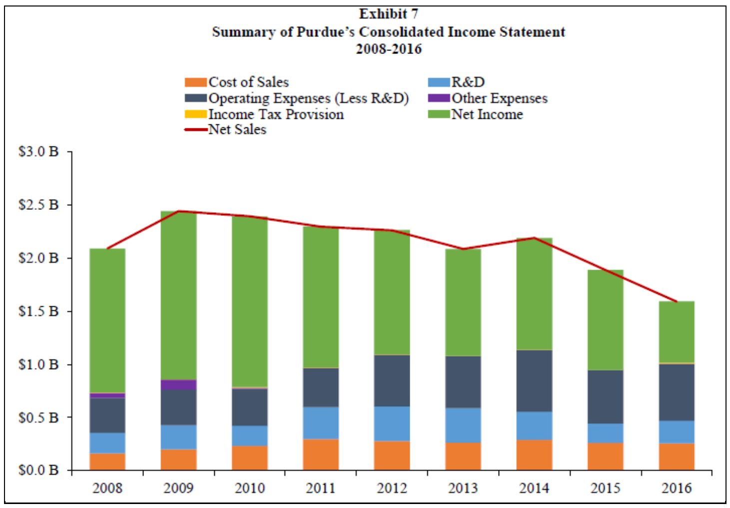
[658] Consent Judgment as to the Purdue Defendants at 2, *State of Oklahoma, ex rel. Mike Hunter v. Purdue Pharma L.P.*, Case No. CJ-2017-816 (Dist. Ct. Cleveland Cnty. Mar. 26, 2019).

[659] *See* Debtors Informational Brief at 1, *In re Purdue Pharma L.P.*, Case No. 19-23649-rdd (Bankr. S.D.N.Y.) (ECF No. 15).

sheer number and scale of the Pending Actions is simply unmanageable."[660]

B. Purdue Was Highly Profitable and Had Large Cash Reserves When Distributions Were Made

449. During the period from 2008 to 2016 when almost all of the Distributions were made (the "**2008-16 Period**"), Purdue generated over $2 billion per year through 2014, and more than a $1.5 billion in revenue in each of 2015 and 2016, as reflected in the chart below.[661]



450. At the time each Distribution was made, Purdue maintained substantial cash reserves. The cash reserves were set by Purdue's CFO and his team to ensure [redacted][662] The CFO has testified that he [redacted]

[660] *Id.* at 37. *See also id.* at 42 ("liability is not a foregone conclusion").

[661] *See* JX-2696 (2008-09 Financial Statements) (PPLPC012000270659) at -663; JX-1843 (2009-10 Financial Statements) (PPLPC012000323951) at -955; JX-1844 (2010-11 Financial Statements) (PPLPMDL0040000537) at -541; JX-1845 (2011-12 Financial Statement) (PPLPC029000544175) at -179; JX-1846 (2012-13 Financial Statement) (PPLPC029000589136) at -140; JX-1847 (2013-14 Financial Statement) (POK003285615) at -620; JX-1848 (2014-15 Financial Statement) (PPLPC011000090527) at -532; JX-1849 (2015-16 Financial Statement) (PPLPC021000890262) at -267. *See also* JX-1944 (Chakraborty Rept. Ex. 7) (citing those documents).

[662] *See* JX-2007 (9/6/19 Edward Mahony Dep. Tr.) at 248:19-250:9.

[redacted][663]

451. From 2009 to 2015, Purdue's year-end balance of unrestricted cash and cash equivalents grew every year, from $339.6 million in 2009 to $1.153 billion in 2014, and it remained over $1 billion in 2015 and 2016.[664] In 2016, the last year a significant distribution was made, Purdue held $1.153 billion in unrestricted cash and cash equivalents at year end, after the Distributions.[665]

452. Purdue generated substantial free cash flows from operations every year in the 2008-16 Period. It had over $1 billion in free cash flow every year from 2008 to 2014, and its free cash flow ranged from a high of $1.715 billion in 2010 to a low of $615 million in 2016.[666]

453. During the 2008-16 Period, the discounted cash flow value of Purdue's assets,

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[663] *See id.* at 270:19-21.

[664] *See* JX-2696 (2008-09 Financial Statements) (PPLPC012000270659) at -662; JX-1843 (2009-10 Financial Statements) (PPLPC012000323951) at -954; JX-1844 (2010-11 Financial Statements) (PPLPMDL0040000537) at -540; JX-1845 (2011-12 Financial Statement) (PPLPC029000544175) at -178; JX-1846 (2012-13 Financial Statement) (PPLPC029000589136) at -139; JX-1847 (2013-14 Financial Statement) (POK003285615) at -619; JX-1848 (2014-15 Financial Statement) (PPLPC011000090527) at -531; JX-1849 (2015-16 Financial Statement) (PPLPC021000890262) at -266; *see also* JX-1861 (Purdue financials and sales information from 2008-2012) (PPLPC031001244649) at p. 10 (providing unrestricted cash from 2008 to 2012); JX-1862 (Purdue P&L Estimates 2015-16) (PPLPC051000265076) at -076 (providing unrestricted cash for 2013 and 2014); JX-1860 (6/8/2016 Mid-year update) (PPLPC045000018249) at -384 (providing unrestricted cash for 2015). *See also* JX-1945 (Chakraborty Rept. Ex. 8).

[665] *See* JX-1849 (2015-16 Financial Statement) (PPLPC021000890262) at -266; *see also* JX-1945 (Chakraborty Rept. Ex. 8).

[666] *See* JX-2696 (2008-09 Financial Statements) (PPLPC012000270659) at -662-65; JX-1843 (2009-10 Financial Statements) (PPLPC012000323951) at -954-57; JX-1844 (2010-11 Financial Statements) (PPLPMDL0040000537) at -540-43; JX-1845 (2011-12 Financial Statement) (PPLPC029000544175) at -178-81; JX-1846 (2012-13 Financial Statement) (PPLPC029000589136) at -139-42; JX-1847 (2013-14 Financial Statement) (POK003285615) at -619-22; JX-1848 (2014-15 Financial Statement) (PPLPC011000090527) at -531-34; JX-1849 (2015-16 Financial Statement) (PPLPC021000890262) at -266-69. *See also* JX-1945 (Chakraborty Rept. Ex. 8).

including excess cash, using a variety of sensitivity-adjusted discount rates ranging from 7.48% to 14.28%, was always more than $1.9 billion and was as high as $9.5 billion:[667]

Exhibit 12
Summary of DCF Valuation of Purdue's Assets
($ millions)

	Valuation ($ millions)		
Year	**Value of Operating Assets**	**Excess Cash**	**Total**
2008	9,157	386	9,543
2009	5,724	282	6,006
2010	7,457	232	7,689
2011	4,693	264	4,958
2012	4,590	349	4,939
2013	2,967	562	3,530
2014	1,377	568	1,945
2015	2,103	750	2,853
2016	1,625	693	2,318

454. The difference between Purdue's assets and liabilities was never less than $1.3 billion, and was as high as $9.2 billion, during the 2008-16 Period:[668]

[667] JX-1937 (Chakraborty Rept. ¶75), JX-1949 (Chakraborty Rept. Ex. 12) (citing JX-2696 (2008-09 Financial Statements) (PPLPC012000270659); JX-1844 (2009-10 Financial Statements) (PPLPC012000323951); JX-1844 (2010-11 Financial Statements) (PPLPMDL0040000537); JX-1845 (2011-12 Financial Statement) (PPLPC029000544175); JX-1846 (2012-13 Financial Statement) (PPLPC029000589136); JX-1847 (2013-14 Financial Statement) (POK003285615); JX-1848 (2014-15 Financial Statement) (PPLPC011000090527); JX-1849 (2015-16 Financial Statement) (PPLPC021000890262)).

[668] JX-1937 (Chakraborty Rept. ¶162); JX-1963 (Ex. 26).

Exhibit 26
Summary of Purdue Balance Sheet Test
($ millions)

Year	Assets			Liabilities				Solvency Cushion
	Operating Assets	Excess Cash	Total Assets	Long-Term Debt	Other Liabilities	Estimated Opioid Litigation Liabilities	Total Liabilities	
	[i]	[ii]	[iii] = [i] + [ii]	[iv]	[v]	[vi]	[vii] = [iv] + [v] + [vi]	[iii] - [vii]
2008	9,157	386	9,543	0	142	200	342	9,201
2009	5,724	282	6,006	0	128	200	328	5,678
2010	7,457	232	7,689	0	131	200	331	7,359
2011	4,693	264	4,958	0	219	200	419	4,538
2012	4,590	349	4,939	0	226	19	245	4,694
2013	2,967	562	3,530	0	163	491	654	2,876
2014	1,377	568	1,945	1	202	491	694	1,251
2015	2,103	750	2,853	0	194	491	685	2,168
2016	1,625	693	2,318	0	169	472	641	1,677

455. In 2017, Purdue's net sales exceeded $1.4 billion,[669] and Purdue retained over $955 million in cash and cash equivalents at year-end 2017.[670] Purdue's cash balance grew to approximately $1.36 billion as of September 13, 2019, just before Debtors filed these bankruptcy cases in September 2019.[671]

456. During the period when the Distributions were made, and through the time that Debtors filed these bankruptcy cases, Debtors had virtually no debt.[672]

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669 JX-1850 (2016-17 Financial Statements) (PPLPC029000692681) at -686.

670 *Id.* at -688.

671 *See* Decl. of Jon Lowne in Support of the Debtors' Chapter 11 Petitions and First Day Pleadings ¶40, *In re Purdue Pharma L.P.*, Case No. 19-23649-rdd (Bankr. S.D.N.Y. Sept. 16, 2019) (ECF No. 3).

672 *See* JX-2696 (2008-09 Financial Statements) (PPLPC012000270659) at -662; JX-1843 (2009-10 Financial Statements) (PPLPC012000323951) at -954; JX-1844 (2010-11 Financial Statements) (PPLPMDL0040000537) at -540; JX-1845 (2011-12 Financial Statement) (PPLPC029000544175) at -178; JX-1846 (2012-13 Financial Statement) (PPLPC029000589136) at -139; JX-1847 (2013-14 Financial Statement) (POK003285615) at -619; JX-1848 (2014-15 Financial Statement) (PPLPC011000090527) at -531; JX-1849 (2015-16 Financial Statement) (PPLPC021000890262) at -266). *See also* JX-1937 (Chakraborty Rept.) ¶87; JX-1951 (Chakraborty Rept. Ex. 14); *id.* ¶178 ("Purdue's debt-equity ratio is zero for all years between 2009 and 2016 given that it had no outstanding debt throughout this period"); *see also* Debtors'

C. Documentary Evidence Establishes That Purdue and the Board Did Not Expect to Face Judgments Purdue Could Not Pay

457. Contemporaneous business records of Purdue lead to the conclusion that the sharp increase in opioid litigation that emerged in 2017 was not expected when the Distributions were made.

458. In a presentation dated January 11, 2008, management advised the Board that it believed that all OxyContin litigation could be "Clos[ed] Out" with a $200 million reserve.[673]

459. The budget attached to the November 3, 2009 Board Agenda shows that management expected Purdue's legal expenses for Product Litigation and Government Related Litigation to decrease year over year. "Product Litigation" costs had been $18.6 million in 2008 and were expected to fall to $15 million in 2009 and $10 million in 2010.[674] "Government Related Litigation" expenses had been $9.1 million in 2005 and $3.5 million in 2008, and were expected to fall to $2.5 million in 2009 and $2 million in 2010.[675]

460. The 10-year plan presented to the Board on June 21, 2011 budgeted largely flat annual legal fees for the years 2011 to 2017,[676] showing that no significant opioid litigation was anticipated.

461. The updated 10-year plan presented to the Board in May 2013 projected a reduction of almost 20% in total legal fees for the same period, from 2013 to 2017. It also

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Informational Brief at 1 ("the Debtors have no funded debt and no material past due trade obligations … [or] any judgment creditors.").

[673] JX-1851 (1/11/2008 Board Agenda Book) (PPLP004400663) at -677.

[674] JX-1852 (11/3/09 Board Agenda Book) (PPLPUCC9002964468) at -495.

[675] *Id*.

[676] JX-2309 (6/21/11 Purdue 10-Year Plan) (RSF00033012) at slide 107.

projected *de minimis* legal fees for Government-Related Litigation—$1.5 million a year or less through 2019.[677] These projections also informed the Board that management expected legal fees spent on Product Liability and Government Related Litigation to fall from $5.5 million in 2013 to under $4.2 in 2022.[678]

462. The 10-year projection that management presented to the Board the following year, in May 2014, projected that legal fees would decline by over 50% from 2013-2023, falling from an estimated $69 million in 2013 to $22 million in 2023.[679]

463. Purdue management's projections for all legal expenses during the 2008-16 Period are summarized as follows:[680]

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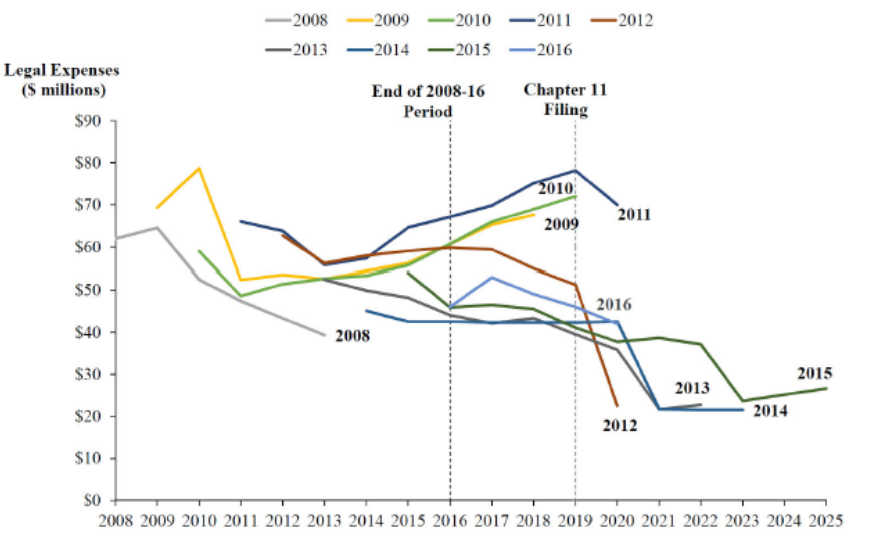
677 JX-1853 (5/9/13 10-Year Plan) (PPLPC063000003469) at -584.

678 *Id*.

679 JX-1854 (5/15/14 Board Agenda Book) (PPLPUCC003118150) at -157.

680 *See* JX-2255 (4/18/08 Five-Year Plan) (PPLPC063000023668) at -685; JX-2270 (7/17/09 Ten-Year Plan) (PPLPC019000293027) at -027; JX-2286 (6/24/10 Ten-Year Plan) (PPLP004404330) at -380; JX-2309 (6/21/11 Ten-Year Plan) (RSF00033012) at slide 107; JX-2329 (2/15/12 Ten Year Plan) (PPLPC053000063393) at -664; JX-1853 (5/9/13 Ten-Year Plan) (PPLPC063000003469) at -526; JX-2407 (5/2/14 Ten Year Forecast) (PPLPUCC002545437) at -440; JX-2422 (6/9/15) (PPLPC054000123288) at slide 52; JX-2436 (6/8/16 Mid-Year Update) (RSF00017771) at -903. *See also* JX-1937 (Chakraborty Rept.) ¶111; JX-1954 (Chakraborty Rept. Ex. 17).

Figure 7. Management Projections for Purdue's Legal Expenses, 2008-2016



464. This chart shows that management projected manageable and stable legal expenditures between 2008 and 2011, and substantially lower legal expenditures beginning in 2012. It is apparent that management did not anticipate anything approaching the massive wave of litigation filings made in 2017-2019. At the time these cases were filed, on September 15, 2019, Debtors were expecting to spend $263 million in 2019 on legal and related professional costs[681]—more than three times the highest projection on this chart.

465. Between the 2011 and 2013 10-year plans, Purdue's annual budget reports reflect that the amounts budgeted for legal fees were in line with the 10-year projections. At the end of 2011, the budget report informed the Board that Purdue's product liability costs were "on budget" and that "only 1 new [product liability] claim" had been filed against Purdue.[682] At the end of 2012, the budget report informed the Board that the latest estimate of 2012 legal fees was

[681] Debtors' Informational Brief at 1-2.

[682] JX-2322 (2012 Budget Submission) (POR172144) at -628-29.

$56.9 million—in line with the projections made in 2011.[683]

466. Purdue's Annual Budgets for 2013, 2014 and 2015 also anticipated legal fees in line with the 10-year plan, showing no expected surge in litigation.[684]

467. Purdue's annual budget report for 2016 showed that Purdue's legal fees in 2013 ($69.4 million) and 2014 ($46.5 million) had been in line with the 2011 projections ($55.8 million and $57.3 million, respectively), and that Purdue's projected legal fees for 2015 ($50.7 million) were substantially lower than the fees projected in 2011 ($64.6 million).[685]

468. Purdue's annual legal fee budget for 2016 ($50.7 million) showed that Purdue projected to spend about 25% less than it had projected in 2011 ($67.1 million).[686] Purdue's Financial Statement for 2016 shows that the actual total spent on legal fees in 2016 ($51.0 million) was almost exactly what was budgeted.[687]

469. Purdue's total accrued litigation settlement and actual legal expenses—including expenses for litigation and legal services not related to opioid litigation, which therefore exceed the historical costs of opioid litigation[688]—for each year from 2006 to 2016 were as follows:[689]

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683 JX-2340 (2013 Budget Submission) (PPLPC063000017048) at -131.

684 JX-2340 (2013 Budget Submission) (PPLPC063000017048) at -607; JX-2418 (2015 Budget Executive Summary) (PPLP004411368) at -463.

685 *Compare* JX-2425 (2016 Annual Budget Report) (PPLPC063000003207) at -373 *with* JX-2309 (6/21/11 Ten Year Plan) (RSF00033012) at slide 107.

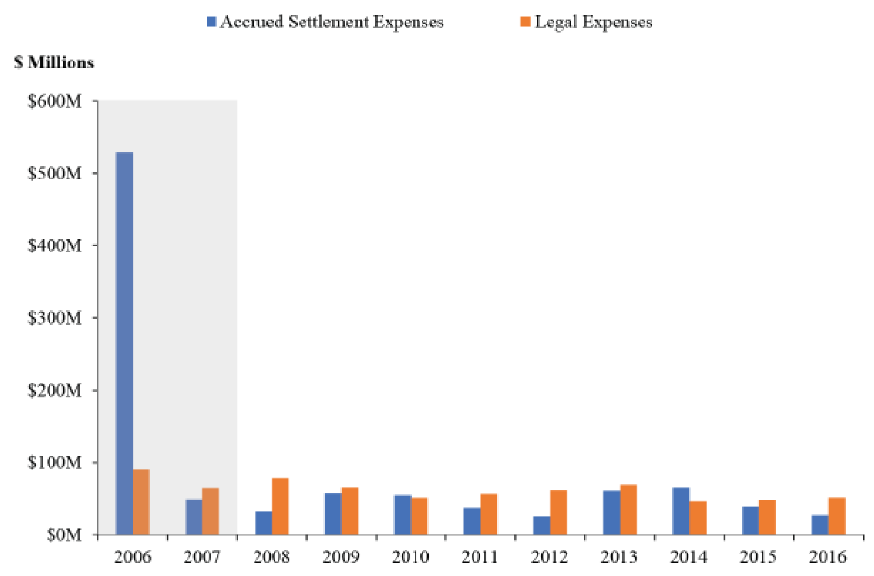
686 *Compare* JX-2425 (2016 Annual Budget Report) (PPLPC063000003207) at -373 *with* JX-2309 (6/21/11 Ten Year Plan) (RSF00033012) at slide 107.

687 JX-2425 (2016 Annual Budget Report) (PPLPC063000003207) at -373; JX-2453 (7/25/17 Executive Committee Meeting Slides) (PPLPC032000398822) at -855.

688 JX-1937 (Chakraborty Rept.) ¶108.

689 *See* JX-2255 (4/18/08 Five-Year Plan) (PPLPC063000023668); JX-2270 (7/17/09 Ten-Year Plan) (PPLPC019000293027); JX-2285 (6/24/10 Ten-Year Plan) (PPLP004404330); JX-2309 (6/21/11 Ten-Year Plan) (RSF00033012); JX-2329 (2/15/12 Ten-Year Plan)

Figure 6. Purdue's Accrued Settlement Expenses and Legal Expenses, 2006-2016[141]



470. This shows that, during the 2008-2016 period, Purdue did not incur large settlements or legal fees, and does not indicate any historical reason why the management or the Board should reasonably have expected any substantial future litigation liabilities.

471. Testimony from Purdue's former CFO confirms that, during the period through 2014, when he was involved in preparing Purdue's financial reports, "no such reserve [for litigation related to the sale and manufacture of OxyContin] was deemed necessary."[690]

472. Management's reports to the Board paint a consistent picture of low litigation risk through 2016. This is accurately summed up by materials for the January 15, 2016 Board meeting. Management reported on "Major Potential Risks to the current cash flow outlook" for Purdue and concluded: "**Risks[:] Litigations (low).**"[691]

(PPLPC053000063393); JX-1853 (5/9/13 Ten-Year Plan) (PPLPC063000003469); JX-2407 (5/2/14 Ten Year Forecast) (PPLPUCC002545437); JX-2422 (6/9/15 Finance Update) (PPLPC054000123288); JX-2436 (6/8/16 Mid-Year Update) (RSF00017771). *See also* JX-1937 (Chakraborty Rept.) ¶108; JX-1953 (Chakraborty Rept. Ex. 16).

690 *See* JX-2007 (9/6/19 Edward Mahony Dep. Tr.) at 287:6-9.

691 JX-2697 (1/15/2016 Board Agenda Book) (PPLP004412586) at -631.

D. Side B Was Intent on Keeping Money Invested in Purdue

473. The documentary record does not show that any Board member anticipated material opioid litigation before the surge of filings in 2017.

474. The record shows just the opposite. The evidence establishes that Board members frequently discussed the future of Purdue; that Side A and Side B had different investment philosophies, but neither Side A nor Side B expressed any concern over future litigation; and that, in 2015, Side B offered to reinvest all Side B distributions back in Purdue in return for subordinated debt, exposing Side B to all risks Purdue faced.

475. In November 2014, Jonathan Sackler informed the Board that Side B opposed further distributions that year. He explained that Side B "prefer[red] to leave the remaining cash in the business" to make more "cash available for acquisitions."[692]

476. Jonathan Sackler further explained: "While there is no certainty in life or in business, the Raymond Sackler family is optimistic about the prospects for the overall business, the quality of management, and the soundness of the strategy adopted by the board. The strategy will take time to bear fruit, but we believe that patience and persistence will be rewarded and the value of the family's pharmaceutical assets will grow in value."[693]

477. A June 2015 email evidences Side B's ongoing efforts to lower distributions from, and to reinvest in, Purdue. The email reflects communications between Side A and Side B directors in which Side B urged that "cash distributions … be tempered," and expressed Side B's

[692] JX-2419 (11/15/14 email from J. Sackler) (RSF_OLK00040227) at -231.

[693] *Id*.

desire to have "the lowest acceptable amount of cash coming out of the company."[694]

478. The June 2015 email also discusses the subordinated debt proposal that Side B made, reflecting its desire to keep its money in Purdue.[695] Side B proposed allowing distributions to both sides of the family, as sought by Side A, and then Side B's lending its distributions back to Purdue in return for subordinated debt, in order to keep cash in Purdue. As set forth in the email, Side B "push[ed] the notion of sub debt as a means of putting both families on equal footing as to their fundamental desires (cash distributions on one hand and strengthening the business on the other)."[696]

479. In August 2015, Side B reworked terms for its subordinated debt proposal.[697]

480. Side B's offer in 2015 to take on subordinated debt of Purdue—which would have exposed Side B to all the risks Purdue faced—is compelling evidence that it did not anticipate the wave of litigation that led to Purdue's bankruptcy.

E. <u>Purdue Invested Billions of Dollars in Research & Development after 2007</u>

481. Allegations that Sackler Family Members stripped Purdue of its assets are irreconcilable with the fact that, in addition to leaving large sums of unrestricted cash in the Company contemporaneously with the Distributions, the Board also approved spending substantial sums on research and development.

482. Research and development expenses ranged from $182 million to $327 million

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[694] JX-1856 (RSF_OLK00021303) (6/28/15 email from S. Ives) at -305, -306.

[695] *Id*. at -303, -305, -306.

[696] *Id*. at -306. *See also* JX-1857 (3/22/15 Term Sheet – Subordinated Debt) (RSF00471984); JX-1858 (7/13/05 email from S. Ives) (RSF00471979).

[697] JX-1859 (8/13/15 email from David Sackler) (RSF_OLK00021534).

annually during the 2008-16 Period.[698] The Board authorized—and Purdue spent—a total of approximately $2 billion dollars on research and development during the period from 2007 to 2017.[699]

483. The Board substantially increased Purdue's research and development budget every year from 2008 ($127.3 million) to 2013 ($377.4 million)[700]—a six-year period over which more than 75% of the Distributions were made.[701]

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[698] *See* JX-2696 (2008-09 Financial Statements) (PPLPC012000270659) at -663; JX-1843 (2009-10 Financial Statements) (PPLPC012000323951) at -955; JX-1844 (2010-11 Financial Statements) (PPLPMDL0040000537) at -541; JX-1845 (2011-12 Financial Statement) (PPLPC029000544175) at -179; JX-1846 (2012-13 Financial Statement) (PPLPC029000589136) at -140; JX-1847 (2013-14 Financial Statement) (POK003285615) at -620; JX-1848 (2014-15 Financial Statement) (PPLPC011000090527) at -532; JX-1849 (2015-16 Financial Statement) (PPLPC021000890262) at -267 . *See also* JX-1937 (Chakraborty Rept. ¶54); JX-1944 (Chakraborty Rept. Ex. 7).

[699] *See* JX-2425 (2016 Budget) (PPLPC063000003207) at -373 (Actual R&D 2008: $120,449,000; 2009: $132,623,000; 2010: $164,784,000; 2011: $269,973,000; 2012: $312,513,000; 2013: $279,200,000; 2014: $150,163,000; 2015 (budget): $107,771,000); JX-2453 (7/25/17 EC Meeting) (PPLPC032000398822) at -855 (Actual R&D 2016: $124,000,000; 2017 (budget): $146,000,000). *See also* JX-2018 (4/18/08 Decision approving revised 2008 budget) (PPLP004416699) at -699, -700 (authorizing $127,281,000 in R&D); JX-2019 (11/6/08 Decision approving 2009 budget) (PPLP004416757) at -757-58 (authorizing $190,000,000 in R&D); JX-2025 (11/3/2009 Decision approving 2010 budget) (PPLP004416983) at -983-84 (authorizing $204,100,000 in R&D); JX-2026 (11/3/10 Decision approving 2011 budget) (PPLP004417106) at -106-07 (authorizing $300,000,000 in R&D); JX-2036 (4/27/12 Decision approving revised 2012 budget) (PPLP004417228) at -228-229 (authorizing $322,500,000 in R&D); JX-2038 (11/16/12 Decision approving 2013 budget) (PPLP004417299) at -299-300 (authorizing $377,347,000 in R&D).

[700] JX-2018 (4/18/08 Decision approving revised 2008 budget) (PPLP004416699) at -699, -700 (authorizing $127,281,000 in R&D); JX-2340 (2013 Budget Submission) (PPLPC063000017048) at -131 (R&D proposed budget: $377,347,000); JX-2038 (11/16/12 Decision approving 2013 budget) (PPLP004417299) at -299, -300 (authorizing $377,347,000 in R&D).

[701] JX-1902 (AlixPartners Cash Transfer Report_ at slides 11, 25 (over $7.8 billion out of a total of $10.3 billion in distributions). *See also* JX-1940 (Chakraborty Rept. Chakraborty Rept. Ex. 3); *compare id.*, JX-1977 (Chakraborty Rept. Appendix H) tab 1, row 1638, column D *with id.*, tab 1, row 599 column D (reflecting that $2,424,459,044 out of $10,318,183,895 in total Distributions were made after 2013).

484. A 2011 report informed the Board that Purdue had "[e]stablished the broadest/largest late stage development program in the company's history."[702]

485. A 2013 report informed the Board that the Research and Development Department was working on the following projects: [redacted].[703]

486. Purdue's substantial investments in long-term projects is evidence of a business being run for long-term success, not a scheme to strip it of its assets.

F. Evidence Offered to Show That the Former Directors Expected And Feared Litigation When Distributions Were Made

487. From the millions of pages of produced materials, a handful of documents from 2006-2008 were identified by the Creditors Committee in a discovery motion (the "**Exceptions Motion**") in an effort to show that members of the Sackler family anticipated the unprecedented wave of litigation a decade later, in 2017-2019, that precipitated Purdue's bankruptcy.[704] The evidence is unconvincing. Further, it does not overcome the voluminous evidence discussed *supra* at ¶¶437-480 persuasively establishing that no Distributions were made with fraudulent

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[702] JX-2322 (2012 Budget Submission) (POR172144) at -160.

[703] JX-2693 (5/13/13 1Q 2013 Board Report) (PPLP004367540) at -581.

[704] *See* Official Committee of Unsecured Creditors' Motion to Compel Production of Purportedly Privileged Documents, or for In Camera Review, Based on Good Cause, Crime Fraud, And At Issue Exceptions To Claims of Privilege at ¶¶2-3, 18-25, 33-34, *In re Purdue Pharma L.P.*, Case No. 19-23649-rdd (Bankr. S.D.N.Y. Dec. 18, 2020), ECF No. 2157; Official Committee Of Unsecured Creditors' Reply In Support Of Its Motion To Compel Production Of Purportedly Privileged Documents, Or For In Camera Review, Based On Good Cause, Crime Fraud, And At Issue Exceptions To Claims Of Privilege at ¶¶7, 48-63, *In re Purdue Pharma L.P.*, Case No. 19-23649-rdd (Bankr. S.D.N.Y. Dec. 18, 2020), ECF No. 2164 ("**Exceptions Reply**").

intent.

1. <u>November 20, 2006 Email from Jonathan Sackler</u>

488. The Creditors Committee argued in the Exceptions Motion (¶19) that an email dated November 20, 2006, from Jonathan Sackler to his brother Richard Sackler about "pharma issues"[705] manifests a concern that future opioid litigation liabilities would overwhelm Purdue. That is unsupported by the text and context of the email.

489. The Creditors Committee argued that this email is proof that the Former Directors authorized the Distributions to evade creditors because Jonathan Sackler (1) wrote that the pharma industry had been "enshrined as a permanent whipping boy for … the bar;" (2) wrote that "[g]etting caught in the crossfire of the war on drugs is obviously a huge risk;" (3) expressed the view that "contingent liabilities continue to hover over the business;" and (4) emphasized the need to "maximize[e] free cash."[706]

490. The Creditors Committee's argument does not account for the date and context of the the November 20, 2006 email.

- Jonathan Sackler wrote in the email that "[t]he financial results in the States will revolve around [patent] exclusivity[.]"[707] In November 2006, patent exclusivity was a major concern for Purdue. Purdue had lost patent exclusivity for OxyContin in January 2006 based on a finding of "inequitable conduct" on Purdue's part.[708] Purdue won that issue in January 2008,[709] and patent exclusivity litigation was

705 JX-2229 (11/20/06 email from Richard Sackler) (PPLPC057000003694).

706 *Id.* at -694, -699.

707 *Id.* at -699.

708 *See* JX-2223 (1/6/04 email from Mortimer D.A. Sackler) (PPLPUCC001504057).

709 *See* JX-2248 (1/8/08 email from Jonathan Sackler) (RSF00424459); JX-2249 (1/11/08 email from Richard Sackler) (PDD9316304985); JX-2247 (1/15/08 email from Richard Sackler) (PPLPUCC003005477).

largely resolved by the end of that year.[710] This is therefore one of the "contingent liabilities" that was "hover[ing] over the business" in November 2006, and it was resolved by the time the Distributions were made.

- On December 21, 2006, one month after Jonathan Sackler sent his email, PPLP's CEO wrote that the DOJ investigation [redacted]—it settled in May 2007, resolving that contingent liability that was [redacted] in November 2006,[711] and it was resolved before the Distributions were made.

- By August 2007, eight months after the November 20, 2006 email, the state consumer protection and Medicaid matters were no longer "hover[ing] over the business" because by then Purdue had entered into 76 settlements with every state other than West Virginia (which had settled in 2004).[712] Only Kentucky continued to litigate its case, which was settled in 2015 for $24 million over eight years.[713]

- At the time Jonathan Sackler wrote the November 2006 email, more than 1,000 products liability lawsuits were "hover[ing] over the business." Purdue settled or disposed of substantially all of them between December 2006 and May 2007.[714] Products liability suits were filed in the wake of the 2007 federal and state settlements but, by January 2008, management informed the Board they could be closed out with a $200 million reserve.[715] By early 2011, these suits had largely been settled in principle.[716] And by early 2012, only 24 products liability cases remained, and all but 3 were dormant.[717]

491. The Creditors Committee also mischaracterized Jonathan Sackler's November

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[710] JX-2695 (2007/08 Financial Statements) (PPLPC012000221168) at -201.

[711] JX-2231 (12/21/06 Year-End Business Update) (PPLPUCC003920061 at -63).

[712] *See* Pt. 1 PFF §§ II.B, II.C; JX-2225 (2004 Settlement Agreement and Release with West Virginia) (VF 00932234).

[713] JX-2430 (Dec. 15, 2015 settlement between Purdue and Kentucky) (PPLPUCC000701839) at -845-46.

[714] JX-2484 (4/13/20 Email from Russell Gasdia) (PPLPC012000372436) at slide 3; JX-2231 (12/21/06 email to all Purdue colleagues) (PPLPUCC003920061) at -063; JX-2694 (2004-05 Financial Statements) (PPLPC012000111317) at -351; JX-1841 (2005-06 Financial Statements) (PPLPC012000144598) at -629.

[715] JX-1843 (2009-10 Financial Statements) (PPLPC012000323951) at -983-4.

[716] *Id.*

[717] JX-1844 (2010-11 Financial Statements) (PPLPMDL0040000537) at -574.

20, 2006 email. It discusses a "need to protect the company"—not the family—"by maximizing free cash." That means Purdue's "free cash" and is the opposite of a suggestion to strip Purdue of assets.[718] And the Board did that. It made sure that Purdue had free cash—from hundreds of millions to over a billion dollars—in unrestricted cash on hand, after distributions, every year, from 2006-2016.[719]

492. The Court finds that the November 20, 2006 email does not manifest any concern about litigation in 2008-2016, when the Distributions were made.

2. **February 27, 2007 Email from Stuart Baker**

493. The Creditors Committee argued in the Exceptions Motion (¶21 n.14) that a February 27, 2007 email from Stuart Baker to Richard Sackler, with the subject "David Board Membership," manifested a concern that Purdue faced massive future opioid litigation. That is not supported by the text of the email.

494. In the email, Stuart Baker wrote: "All you need to do is tell me that Raymond, Beverly, and Jon agree, and I will prepare the necessary papers. Please be sure to tell them (including David) that I recommend against David becoming a Director at this time."[720] The email says nothing about litigation and does not give rise to any inference that litigation had anything to do with his recommendation. At the time, David Sackler was 26 years old, worked at a hedge fund and had no experience at Purdue other than as a summer intern.

495. Even crediting the unsubstantiated inference that Baker's recommendation was

[718] *Id.*

[719] *See supra* at ¶451 (2008-16); JX-1842 (2006-07 Financial Statements) (PPLPMDL0040000379) at -382.

[720] JX-2232 (02/27/07 email from Stuart Baker) (PPLPUCC000555709).

motivated by litigation risk would not prove Distributions were made with fraudulent intent, as the email is another communication that predates Purdue's resolution of patent exclusivity litigation and the 2007 state and federal settlements of the OxyContin litigation.[721] Further, if one were to credit the unsubstantiated inference that Baker's recommendation against David Sackler's joining the Board in 2007 was motivated by litigation risk, on the same logic, since there is no evidence that Baker objected when David Sackler joined the Board in 2012, that would lead to the conclusion that there was no concern about litigation risk in 2012.

496. The Court finds that the February 27, 2007 email does not manifest any concern about litigation in 2008-2016, when the Distributions were made.

3. <u>March 25, 2007 Email from Jonathan Sackler</u>

497. The Creditors Committee argued in the Exceptions Motion (¶49) that a March 25, 2007 email from Jonathan Sackler to other directors manifested a concern that future opioid litigation liability would overwhelm Purdue. The Court finds that the text and context of the email do not support that inference.

498. In the email, Jonathan Sackler states that, "as WDVA empties our coffers," "[t]here are a number of risks" that "we're really not braced for," including "[t]he emergence of numerous lawsuits."[722] The email was written before the 76 settlements Purdue entered into in 2007 with 49 states that resolved all non-federal governmental OxyContin litigation except with Kentucky. To the extent that "[t]he emergence of numerous lawsuits" anticipated product liability lawsuits, this email precedes management's advice to the PPI board in January 2008 that

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[721] *Id.*; *see supra* at ¶490 (December 2006 reference to 2007 settlements).

[722] JX-2235 (3/25/07 email from Jonathan Sackler) (PPLPUCC004057767) at -767.

all OxyContin litigation could be "Clos[ed] Out" for $200 million,[723] and the settlement, dismissal or collapse into dormancy of those product liability suits by 2011-12. *See supra* at ¶440.

499. The Court finds that the March 25, 2007 email does not manifest any concern about litigation in 2008-2016, when the Distributions were made.

4. <u>March 22, 2007 Email from Jonathan Sackler</u>

500. The Creditors Committee argued in the Exceptions Reply (¶49) that a March 22, 2007 from Jonathan Sackler manifested a concern that future opioid litigation liability would overwhelm Purdue. In the email, Jonathan Sackler wrote that he wanted Purdue to hire a consulting firm "to review strategic options for the business, like a McKinsey," in light of:

> [1] the ongoing risks created by the WDVA (in other words, if there's a future perception that Purdue has screwed up on compliance, we could get murdered) … [2] an uncertain contingent liabilities picture … [3] an uncertain exclusivity asset … [and 4] unexploited generics opportunities.[724]

501. The Court finds that the text and context of the email do not support the suggested inference. Issue [1]—"future perception"—appears to address a public perception concern. There is no apparent reason to conclude that issues [2] and [3]—"contingent liabilities" and "uncertain exclusivity asset"—reference to anything other than same "contingent liabilities" and patent "exclusivity" issues addressed in Jonathan Sackler's email of November 20, 2006 (¶490) which also uses the phrase "contingent liabilities" hovering and expresses concern about "exclusivity."

502. The first three issues were the same litigation risks that were resolved between May 2007 and late 2008, after this email was sent. The fourth issue—unexploited generic

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[723] JX-1851 (1/11/08 Board Agenda Book) (PPLP004400663) at -677.

[724] JX-2234 (3/22/07 email from Jonathan Sackler) (PPLPUCC9004824942) at -942.

opportunities—was a business risk.

503. The Court finds that the March 22, 2007 email does not manifest any concern about litigation in 2008-2016, when the Distributions were made.

5. May 17, 2007 Email from David Sackler

504. The Creditors Committee argued in the Exceptions Motion (¶21) that a May 17, 2007 email written by David Sackler just after Purdue's 2007 Guilty Plea showed that he was anticipating future litigation against Purdue because he wrote to his father and uncle, "We will be sued."[725] The Creditors Committee's argument is not supported by the text or context of the email.

505. At the time he wrote this email, David Sackler was 26 years old and working at a hedge fund. He had never worked at Purdue except as a high school intern.[726] He testified:

> I really didn't know much about what was happening. I don't think at this point I even knew that the payment to the federal government was being paid out of Purdue cash … I just wasn't involved in any of the legal side of it. I just, you know, I got a call one day from my father telling me we're settling and it's going to be in the newspaper the next day. That was about it.[727]

506. He sent the email a week after Purdue's 2007 Guilty Plea and federal settlement, and he was apprehensive that the 2007 Guilty Plea would be followed by suits against the family. It is evident from the text that the word "We" in his statement "We will be sued" referred to the family, not Purdue, being sued. He is writing in response to the email from his uncle, Jonathan Sackler, stating "you should rest assured that there is no basis to sue 'the family,"[728] and David

[725] JX-2237 (5/17/07 email from David Sackler) (PPLPUCC002683256).

[726] JX-1989 (8/28/20 David Sackler Dep. Tr.) at 61:24-62:7.

[727] JX-1989 (8/28/20 David Sackler Dep. Tr.) at 186:17-187:8.

[728] *See also* JX-2237 (5/17/07 email from David Sackler) (PPLPUCC002683256).

Sackler expresses concern that plaintiffs' lawyers might "freeze our assets and threaten us," forcing a settlement.[729]

507. As it turned out, David Sackler's concern was misplaced and Jonathan Sackler's statement was vindicated. None of the hundreds of products liability suits filed in the wake of Purdue's 2007 guilty plea named the family—and all were settled, dismissed or dormant within a few years. *See supra* at ¶¶439-40.

508. In 2012, five years after writing JX-2237, David Sackler joined the PPI Board. *See supra* at ¶356. The logical inference is that he would not have done so if he anticipated future massive opioid litigation against Purdue

509. In 2015, eight years after writing this email, he (together with Richard and Jonathan Sackler) proposed that Side B lend its distributions back to Purdue in return for subordinated debt. That would have exposed Side B to all of Purdue's litigation risk. *See supra* at ¶480.

510. That offer is persuasive evidence that David, Jonathan and Richard Sackler did not anticipate massive opioid litigation against Purdue in 2015.

511. Neither the text nor the context of the May 17, 2007 email supports an inference that David Sackler was anticipating massive future litigation liability on the part of Purdue at the time it was written. The Court finds that the November 20, 2006 email does not manifest any concern about litigation in 2008-2016, when the Distributions were made.

6. <u>May 13, 2007 Email from Richard Sackler</u>

512. The Creditors Committee argued in the Exceptions Motion (¶20) that a May 13, 2007 email from Richard Sackler to a friend three days after Purdue's 2007 Guilty Plea—and

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[729] *Id.*.

around the time the 2007 state settlements were being consummated—reflects concern about "liability related to the opioid crisis." That is not supported by the text of the email.

513. The subject of the email is "news coverage," not litigation.[730] There is no mention of litigation. It is evident that Richard Sackler was referring to news coverage when he wrote: "I'm not confident that this is something that will blow over. My sense is that it may get a lot worse in the coming weeks."[731] That is shown by the fact that the same email chain contains an optimistic message he wrote two days later: "The good news is that things simmered down very quickly … my fears seem to be for naught. I'm very much relieved, and now we are planning on how to handle the future for the business."[732] Given the subject line of the emails and the timing, there is no apparent basis to assume this refers to litigation but, even if it did, it shows that his concern had subsided within 48 hours.

514. The Court finds that the May 13, 2007 email does not manifest any concern about litigation in 2008-2016, when the Distributions were made.

7. June 22, 2007 Email from David Sackler

515. The Creditors Committee argued in the Exceptions Motion (¶23) that an email from David Sackler dated June 22, 2007[733] showed that he was worried that Purdue's future liabilities could affect a merger.[734] That is not supported by the text of the email.

516. The email clearly states that David Sackler's concern was that negative publicity

[730] JX-2236 (5/13/07 Email from R. Sackler to E. Kohlberg) (PWG004474511).

[731] *Id*. at -511.

[732] *Id*.

[733] JX-2239 (6/22/07 Email from David Sackler) (PWG004473999).

[734] *See* Exceptions Motion ¶23.

associated with Purdue's 2007 Guilty Plea could "decimate" a merger:

> [W]e have absolutely no idea how our negative publicity will play with investors. It may be that we're tainted and the negative press around Oxy will decimate a smaller company's stock price.... If we merge with a company like SEPR the analysts could very well start saying crazy things about future liabilities and we could see the value of our investment seriously diminished.[735]

517. The Court finds that the June 22, 2007 email does not manifest any concern about litigation in 2008-2016, when the Distributions were made.

8. <u>June 25, 2007 Email from David Sackler</u>

518. The Creditors Committee argued in the Exceptions Motion (¶66) that an email from David dated June 25, 2007, manifested concern about Purdue's future liabilities.[736] That is not supported by the text or context of the email.

519. The email, which David Sackler wrote to his father Richard Sackler, his uncle Jonathan Sackler, and his cousin Mortimer Sackler, Jr., discusses potential merger opportunities for Purdue and poses the "fundamental[]" question whether the families "want to be in the pharmaceutical business going forward."[737] He wrote: "I would vote no. I think we've all had enough of a rough ride over the past 10 years to make me wary of committing for another venture in the space."[738] He also wrote: "Since you guys are closer to this than I am, I obviously will support the decision 100% if the family decides to retrench in the industry.[739]

520. As found in ¶¶494, 505, *supra*, at the time he wrote this email, David Sackler

[735] JX-2239 (6/22/07 Email from David Sackler) (PWG004473999) at -4000.

[736] JX-2240 (6/25/07 Email from David Sackler) (PPLPUCC000886987).

[737] JX-2240 (6/25/07 Email from David Sackler) (PPLPUCC000886987).

[738] JX-2240 (6/25/07 Email from David Sackler) (PPLPUCC000886987).

[739] JX-2240 (6/25/07 Email from David Sackler) (PPLPUCC000886987).

was 26 years old and working at a hedge fund and had never worked at Purdue except as a high school intern.[740] In the June 25, 2007 email, he defers to his father, uncle and cousin's thoughts at the time.[741] They elected to remain in the business. This 2007 email does not support an inference that he was anticipating massive future litigation liability on the part of Purdue.

521. The Court finds that the June 25, 2007 email does not manifest any concern about litigation in 2008-2016, when the Distributions were made.

9. July 24, 2007 Peter Boer Memorandum

522. The Creditors Committee argued in the Exceptions Motion (¶23) that a July 24, 2007 memorandum that Peter Boer wrote to Jonathan Sackler about a potential sale of Purdue manifested a concern that future litigation liabilities would overwhelm the Company.[742] That inference is not supported by the text or context of the email.

523. At the time the memorandum was written, Peter Boer was a former executive with W.R. Grace & Co. (a chemical company).[743] The following year, he became an outside director of PPI. The memorandum expresses Peter Boer's thoughts to Jonathan Sackler based on Boer's prior experience at Grace, which had substantial asbestos liability.[744] In the memorandum, Peter Boer stated that legal liabilities would impact the sale value of Purdue "until interest in litigation has died down."[745] As discussed in ¶440, *supra*, by 2010-11, only three of the products liability suits filed after the 2007 Guilty Plea were still being actively litigated, and

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[740] JX-1989 (8/28/20 David Sackler Tr.) 61:24-62:7.

[741] *See* JX-2240 (6/25/07 Email from David Sackler) (PPLPUCC000886987) (stating that he will "support the decision 100%" if his cousin, father and uncle want to "retrench in the industry");.

[742] *See* JX-2241 (7/24/07 Memo from Peter Boer) (PPLPUCC9000491386).

[743] JX-2479 (Peter Boer Resume) (PPLPUCC9003818077)

[744] JX-2241 (7/24/07 Memo from Peter Boer) (PPLPUCC9000491386) at –388.

[745] *Id.* at -389.

none of the Pending Opioid Actions were filed until years later.

524. The Exceptions Motion (Preliminary Statement ¶3) argued that the memorandum "recommend[ed]" the Sacklers take "defensive measures." There is no such recommendation in the memorandum, and there is no evidence that anyone took any defensive measures after receiving the memorandum.

525. The memorandum states that: "it may be that overseas assets with limited transparency and jurisdictional shielding from U.S. judgments will be less attractive to litigants than domestic assets. Obviously, this factor depends on how the ownership is structured, and I presume the family has taken most of the appropriate defensive measures."[746] There is no evidence that Peter Boer had any actual knowledge of the organizational structure of the family's holdings, and the phrasing of the memorandum implies that he did not. The B-side trusts that own Purdue are domestic and date to 1974 and 1989—years before OxyContin was introduced.[747] There is no evidence that anyone took any "defensive measures" in response to this memorandum.

526. The Court finds that the July 24, 2007 memorandum was written by a non-family member, generated no action by the family, and does not manifest any concern about litigation on the part of Purdue or Side B in 2008-2016, when the Distributions were made.

10. <u>April 12, 2008 Memo from Richard Sackler and Peter Boer</u>

527. The Creditors Committee argued in the Exceptions Motion (¶25) that an April 2008 memorandum from Richard Sackler and Peter Boer manifested a concern that massive

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[746] *Id.*

[747] *See* JX-1915 (Martin Report, Ex. A — Nov. 20, 2019 Raymond-Side Informational Presentation) at slides 4, 23-29.

opioid litigation liabilities would engulf Purdue. This argument is not supported by the text of the memorandum.

528. The Creditors Committee argued that the memorandum "lamented Purdue's 'dangerous concentration of risk'" and recommended "distribut[ing] more free cash flow"[748] The memorandum makes it clear that the "risk" it was discussing was not opioid litigation. The memo identified the risk as the anticipated end of "our period of [OxyContin's patent] exclusivity, currently estimated to be through 2013."[749]

529. The subject of the memo is CEO loyalty in the context of a possible sale or recapitalization of Purdue.[750] The memo states that: "A successful CEO will diversify sources of cash flow over the next five years to reduce the company's vulnerability to loss of exclusivity, and increase investor estimates of EBITDA beyond this timeframe."[751] The memo states that a CEO must "achieve results within the short time frame afforded by our exclusivity position," and emphasized that "[m]ajor risks must be avoided, especially non-compliance with the Corporate Integrity Agreement,"[752] showing the importance of compliance to the directors.

530. The memo says nothing about opioid litigation. It does not evince any concern about opioid litigation risk. The Court finds that the April 12, 2008, memorandum does not manifest any concern about litigation in 2008-2016, when the Distributions were made.

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[748] Exceptions Motion ¶25 (citing JX-2254 (4/12/08 Memo from Peter Boer) (PDD9316314303)).

[749] JX-2254 (4/12/08 Memo from Peter Boer) (PDD9316314303) at -304 (first paragraph under the heading "Priority 1"), -305, -306.

[750] *Id.* at -303.

[751] *Id.* at -305.

[752] *Id*. at -305-06.

G. Economic Evidence Supports the Conclusion that the Sharp 2017 Increase in Pending Opioid Actions Was Not Foreseeable in 2008 to 2016

531. Economic evidence indicates that the massive number of Pending Opioid Actions brought in 2017-19 was not anticipated by the market, including sophisticated market participants, in 2008-16.

1. Assessments of Purdue by Investment Banks and Rating Agencies

532. In July 2009, Goldman Sachs prepared an assessment of Purdue's business.[753] Goldman Sach's assessment did not identify a risk that Purdue could be subject to new opioid litigations. The only litigation risk that the Goldman Sachs assessment identified was patent litigation between Purdue and other opioid manufacturers.[754]

533. In 2014, Purdue retained JPMorgan to prepare a "comprehensive valuation and debt capacity analysis" in connection with a potential capital raise in the debt markets.[755]

534. JPMorgan concluded that "the Company has access to" the bank loan market, the institutional loan market, and the high yield market. JPMorgan opined "the Company can raise approximately $1 - $1.5bn" in debt financing. [756] JPMorgan's 2014 analysis is inconsistent with any suggestion that it viewed Purdue as facing massive opioid litigation liabilities. The only litigation risk identified by JP Morgan was ongoing patent exclusivity litigation with other manufacturers concerning OxyContin.[757]

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[753] JX-1904 (7/14/09 Goldman, Sachs & Co. "Discussion Materials for Purdue") (PPLPC042000017723).

[754] *Id.* at -733.

[755] JX-1905 (8/13/14 JPMorgan Debt Capacity Presentation) (PPLPC022000838293) at -301.

[756] *Id*. at -335.

[757] *Id*. at -336.

535. In 2016, Purdue received an indicative credit rating from Moody's of "Ba3" rating.[758] Moody's stated: "The Ba3 indicative Corporate Family Rating is supported by Purdue's low financial leverage …. This will allow the company to absorb considerable operating or legal setbacks with minimal risk of debt impairment."[759]

536. In 2016, Standard & Poor's gave Purdue a BB corporate credit rating and a BBB-/1 Senior Secured/Recovery ration. Standard & Poor's stated: "A historically conservative financial policy (this is the first debt placement) and very low leverage metrics support our 'minimal' financial risk assessment."[760]

537. Neither Moody's nor Standard & Poor's discussed any risk of current or future opioid litigation or investigations as a risk to Purdue's ability to repay debt.[761]

2. Market Valuations of Publicly Traded Equity Securities and Credit Ratings for Other Opioid Manufacturers

538. The economic evidence reflects that the financial markets, in their treatment of opioid manufacturers also named as defendants in the Pending Opioid Actions ("**Litigation Comparables**"),[762] did not anticipate massive opioid litigation before 2017.

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758 JX-1906 (3/30/16 Moody's Investors Service Indicative Ratings Letter) (PPLPUCC003938943) at -943.

759 *Id*.

760 JX-1907 (4/7/16 Standard & Poor's Indicative Ratings Letter) (PPLPUCC000360920) at -922; *see also* JX-1937 (Chakraborty Rept.) ¶117.

761 *See* JX-1906 (3/30/16 Moody's Investors Service Indicative Ratings Letter) (PPLPUCC003938943); JX-1907 (4/7/16 Standard & Poor's Indicative Ratings Letter) (PPLPUCC000360920).

762 *See* JX-1937 (Chakraborty Rept.) ¶¶121-22 (identifying Endo, Insys, Mallinckrodt and Teva as Litigation Comparables).

539. The credit ratings of Mallinckrodt,[763] Endo,[764] and Teva[765]—as issued by Moody's and Standard & Poor's—did not significantly dip until 2019.[766]

540. Moody's and Standard & Poor's did not mention the risk of opioid litigation in credit rating reports for Mallinckrodt and Teva, until 2018-2019, and for Endo until November 29, 2017.[767]

541. The Litigation Comparables were able to raise new capital during the 2008-16 Period. Endo issued $2 billion in stock in June 2015.[768] Teva raised $3.38 billion in an equity offering in December 2015.[769]

542. In 2015, Endo, Teva, and Mallinckrodt each borrowed more than $2 billion in corporate debt.[770] In addition, to fund an acquisition, Teva raised $20 billion in debt in 2016,

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[763] *See Id.* at¶¶141-142 and Ex. 22b.

[764] *See Id.* at ¶¶141-142 and Ex. 22a.

[765] *See Id.* at ¶¶141-142 and Ex. 22c.

[766] *See Id.* at ¶¶141-142 and Exs. 22a, 22b and 22c.

[767] *See Id.* at ¶¶141-142 and Exs. 23a, 23b and 23c.

[768] *See* JX-2202 (6/8/15 Endo International plc, SEC Form 424(b)(5)) at p. 2. ("We are offering 24,024,025 ordinary shares (the 'Ordinary Shares') of Endo International plc (the 'Company'). We intend to use a portion of the net proceeds of this offering, together with the net proceeds of the Debt Financings (as defined herein), to finance the Acquisition [of Par Pharmaceuticals] (as defined herein), refinance certain outstanding debt and to pay related fees and expenses").

[769] *See* JX-2204 (12/3/15 Teva Pharmaceutical Industries Limited, SEC Form 424(b)(5)) at p. 2 ("We are offering 54,000,000 of our American Depositary Shares ('ADSs'), each representing one of our ordinary shares, nominal (par) value NIS 0.10 per share ('ordinary shares'). … We intend to use the net proceeds of this offering together with the net proceeds of the concurrent Mandatory Convertible Preferred Shares offering and the proposed debt financings (each as described herein), to finance our pending acquisition of Allergan plc's worldwide generic pharmaceuticals business, and related fees and expenses, to finance our pending Rimsa acquisition (as described below) and/or otherwise for general corporate purposes").

[770] *See* JX-2206 (Endo International plc, SEC Form 10-K, for the fiscal year ended December 31, 2015) at pp. F-51 and F-53; JX-2205 (Teva Pharmaceutical Industries Limited, SEC Form 20-F,

with the investor demand greater than the offering size, according to Teva.[771]

543. The stock prices of Endo, Insys, and Mallinckrodt, all increased through early to mid-2015 and then drifted downward, and Teva's stock price fluctuated until 2015 and then declined starting in 2016, but equity analysts attributed the stock price declines to factors unrelated to the risk of opioid litigation.[772]

H. Tax Distributions Were Customary and Approximate Taxes PPLP Would Have Paid If It Had Been Organized As a C Corporation

544. Because PPLP was organized as a pass-through entity, the tax obligations arising from PPLP's income fell on its partners.[773]

Table 2: Comparison of Actual Tax Distributions and Hypothetical Corporate Tax Liability
(Millions of USD)

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	Total	Calculations
PPLP Tax Distributions[I]	540	711	654	556	460	401	436	366	249	187	0	4,559	[A]
Hypothetical Corporate Tax Liability - Trompetta Declaration[II]	578	689	656	537	500	380	410	382	239	120	36	4,526	[B]
Difference	38	(22)	2	(19)	41	(21)	(25)	15	(10)	(67)	36	(33)	[C] = [B] - [A]
Percentage Difference	7.0%	-3.1%	0.4%	-3.5%	8.8%	-5.3%	-5.8%	4.2%	-4.1%	-35.8%	100.0%	-0.7%	[D] = [C] / [A]

<u>Notes and Sources:</u>
[I] Alix Report, p. 29.
[II] *See* Table 1.

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for the fiscal year ended December 31, 2015) at p. 75; JX-2203 (Mallinckrodt plc, SEC Form 10-K, for the fiscal year ended September 25, 2015) at pp. 102-103; *see also* JX-1937 (Chakraborty Rept.) ¶144.

771 *See* JX-2207 (7/21/16 Teva Pharmaceutical Industries Ltd, SEC Form 6-K).

772 JX-1937 (Chakraborty Rept.) ¶¶132, 134.

773 *See* JX-0425 (Expert Report of Jennifer Blouin) ("**Blouin Report**") ¶¶10(a), 30, 67 & Table 11; Supp. Declaration of Jennifer Blouin ("**Blouin Supp. Decl.**") ¶¶7-8 & Table 2. *See also* 26 U.S.C. § 701 ("Partners, not partnership, subject to tax"); *BASR P'ship v. United States*, 795 F.3d 1338, 1340 (Fed. Cir. 2015) ("[A]ny tax liability arising from items on a partnership return 'passes through' to the individual partners, who are then liable for their 'distributive share' of the partnership's gains and losses.").

545. As the foregoing chart reflects, in the years 2008, 2010, 2012, 2015, and 2018, the Tax Distributions that PPLP paid were less than the hypothetical taxes it would have incurred. Thus, "the value of the tax distributions paid by PPLP during the [2008-17] Period was reasonably equivalent to the amount of taxes PPLP would have faced if it were organized as a C corporation during the [same period]."[774]

546. The amounts of Tax Distributions roughly correlate with the amount PPLP would have been obliged to pay had it been organized as a tax-paying corporation:[775]

547. As is typical for pass-through business organizations, PPLP paid Tax Distributions to provide its owners with liquidity to pay the taxes arising from its (that is PPLP's) income.[776]

548. The Tax Distributions were paid pursuant to distribution agreements among members of the Sackler Families that required tax distributions in an amount "at least equal to the income tax liability at the highest tax rate of any of the partners or the members, as the case may be, for that calendar year."[777]

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[774] JX-0425 (Blouin Report) ¶71; Blouin Supp. Decl. ¶8.

[775] JX-0425 (Blouin Report) ¶67 & Table 11; Blouin Supp. Decl. ¶¶7-8 & Table 2. *See generally* JX-0425 (Blouin Report) ¶¶60-71.

[776] *See id.* ¶¶43-50.

[777] JX-2081 (1998 Distribution Agreement) (RSF00664015) at 016; *see also* JX-2080 (1997 Distribution Agreement) (RSF00664007) at 009; JX-2078 (1991 Distribution Agreement) (RSF00663993). The payment of tax distributions was also required by the March 4, 2003 Shareholders' Agreement for PPI, which provided that PPLP would make distributions in accordance with Section 2A of the 1998 Distribution Agreement, the provision requiring tax distributions. JX-2082 (2003 PPI Shareholders' Agreement) (PPLPUCC9002364133) at -148. *See generally* JX-0425 (Blouin Report) ¶¶46-49.

549. Approximately 90% or more of the Tax Distributions were actually used to pay taxes. According to the AlixPartners Cash Transfer Report, more than half of the Tax Distributions were paid directly to taxing authorities.[778] Between 2008 and 2017, two Side B entities—the 74A Trust and Rosebay Medical Company, Inc.—received $2,261 million in tax distributions[779] from PPLP and incurred $2,072 million in taxes (*i.e.*, approximately 92% of the amount received in Tax Distributions).[780] As a result, approximately 90% or more of the Tax Distributions were actually paid to the federal, state and local governmental Claimants in these bankruptcy cases.

550. PPLP received a benefit from the tax arrangement under which it paid Tax Distributions. The tax burden resulting from PPLP's income fell on its owners, and in exchange they received tax distributions. As Professor Blouin explained, the payment of tax distributions is typical of pass-through businesses and, from her perspective as an economist and a tax expert, this was "an exchange of reasonably equivalent value because the tax distributions were made in exchange for bearing the tax obligation created by PPLP's economic activity."[781]

X. WITNESS TESTIMONY

551. Professor Lawrence Hamermesh, an expert in corporate governance, offered testimony as an expert witness through his written report. JX-0470 (Hamermesh Report).

[778] *See* JX-1902 (AlixPartners Cash Transfer Report) at 67.

[779] JX-0425 (Blouin Report) ¶46; *id.* ¶46 n.64 ("[S]ome of the tax distributions received by Trust 74A and RMCI were in the form of direct payments to taxing authorities made on their behalf and that others were in the form of cash which, being fungible, can be used to pay any expenses.")..

[780] *Id.* ¶46. It is commonplace for some partners receiving tax distributions to receive slightly more in tax distributions than they incur in taxes. This is because tax distributions are typically based on the highest marginal tax rate faced by any partner, meaning that those partners who are taxed at a lower rate will receive more in distributions than is required to pay their (lower) taxes. *See id.* ¶45.

[781] *Id.* ¶¶52-53, 59; Blouin Supp. Decl. ¶8.

Professor Hamermesh is a credible witness and his expert report establishes his qualifications to testify as an expert and the basis for his expert testimony. No evidence has been offered establishing that he was unqualified to offer his expert opinion, that his testimony was not credible, or that his testimony should not be considered for some other reason.

552. Professor Jennifer Blouin, an expert in taxation, offered testimony as an expert witness through her written report. JX-0425 (Blouin Report). Professor Blouin supplemented her written report with a declaration addressing information set forth in the declaration of Carl Trompetta, who is also a credible witness, that she received after her written report. Professor Blouin is a credible witness and her expert report establishes her qualifications to testify as an expert and the basis for her expert testimony. No evidence has been offered establishing that she was unqualified to offer her expert opinion, that her testimony was not credible, or that her testimony should not be considered for some other reason.

553. Dr. Maureen Chakraborty, an economist and solvency expert, offered testimony as an expert witness through her written report. JX-1937 (Chakraborty Report). Dr. Chakraborty is a credible witness and her expert report establishes her qualifications to testify as an expert and the basis for her expert testimony. No evidence has been offered establishing that she was unqualified to offer her expert opinion, that her testimony was not credible, or that her testimony should not be considered for some other reason.

554. Tim Martin, a financial expert, offered testimony as an expert witness through his written report. JX-1914 (Martin Report). Mr. Martin is a credible witness and his expert report establishes his qualifications to testify as an expert and the basis for his expert testimony. No evidence has been offered establishing that he was unqualified to offer his expert opinion, that his testimony was not credible, or that his testimony should not be considered for

some other reason.

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555. **Final Finding of Fact.** To the extent that any Conclusion of Law may be deemed a Finding of Fact, it is hereby incorporated by reference.

PROPOSED CONCLUSIONS OF LAW

556. The Former Directors have identified strong defenses to both the Non-Estate Claims and Estate Claims, raising doubt as to whether or to what extent any Claim would succeed if litigated.

557. The Court concludes that, if the Plan were not confirmed, the Sackler Families would have substantial defenses and evidence to back them up, the litigation would be highly protracted, the outcome would be uncertain, and that there is substantial reason to believe the Plan provides claimants—including the estates—with more value than they are likely to obtain in litigation.

558. Accordingly, the Court concludes that the releases and channeling injunctions in the Plan can and should be approved.

I. THE NON-ESTATE CLAIMS

559. The Non-Estate Claims primarily sound in deceptive marketing, negligent diversion, and public nuisance.

560. The following conclusions concerning the Non-Estate Claims focus on conduct during the Relevant Period—after Purdue's 2007 Guilty Plea and 77 OxyContin settlements with the federal government and every state other than West Virginia (which had settled in 2004).

561. Conduct preceding 2007—a decade or more before claims were brought against members of the Sackler family—is likely irrelevant because the pre-2007 conduct was the subject of releases and because claims based on that conduct are likely untimely.

A. Claims Requiring Proof of Culpable Scienter Are Likely to Fail

562. Many Non-Estate Claims require a showing that the Former Directors did not act in good faith or were negligent,[782] grossly negligent,[783] reckless,[784] or acted with actual intent to deceive.[785]

563. These Claims have a low likelihood of success because the Former Directors have presented substantial evidence that they did not know, or have reason to know, that Purdue's marketing was deceptive.

564. Because PPI was a New York corporation, New York law governs its internal affairs.

565. Under New York law, each Former Director was entitled to rely on information, opinions, reports and statements of officers, employees and outside professionals. N.Y. B.C.L. §717(a)(1) & (2).

566. The record before the Court confirms the reasonableness, good faith and conscientiousness of the Board. *See, e.g.*, ¶¶59, 68-70, 119-121 (compliance reports); ¶¶35-39,

[782] *See, e.g.*, CO AG FAC Count 9; ID AG Compl. Count 3.

[783] *See, e.g.*, NYAG Count 12

[784] *See, e.g.*, RI AG SAC Count 2.

[785] *See, e.g.*, *M & T Mortg. Corp. v. White*, 736 F. Supp. 2d 538, 560-61 (E.D.N.Y. 2010) (fraud under New York law requires a misrepresentation or omission of material fact "made deliberately or knowingly (with *scienter*)"); MASS. GEN. LAWS ANN. ch. 93A, §4 (permitting civil penalties only "[i]f the court finds that a person has employed any method, act or practice which he knew or should have known to be in violation of said section two."); UTAH CODE ANN. §13-11-4(2) ("a supplier commits a deceptive act or practice if the supplier knowingly or intentionally").

126 (federal oversight); ¶¶59(a), 125-127 (HHS OIG confirmation of compliance); ¶¶59(b), 134-141 (voluntary continuation of compliance program and hiring of outside counsel for effectiveness reviews); ¶¶89-91 (extensive employee compliance training); ¶¶97-103, 105 (audits of potential areas of risk); ¶104 (compliance monitoring of speakers' program); ¶¶114-118 (Board advised all compliance issues were reported and remediated); ¶¶119-124 (Board advised all aspects of compliance program were properly functioning and exceeded industry standards); *see also* JX-0470 (Hamermesh Report) at ¶30 (opining that "the actions of the Former Directors in regard to the implementation and monitoring of a reporting system and controls over marketing and distribution of opioids satisfied or exceeded the norms of customary corporate governance practice"); *id*. at ¶¶31-42.

567. The record also shows that the Board reasonably understood that Purdue had systems in place to ensure the accuracy of its marketing, including requiring its Medical, Legal and Regulatory Affairs Departments to each review and approve all marketing material (¶¶79-80, 284), mandating that "[a]ll product claims made verbally by Sales Force Personnel must be consistent with product labeling" and prohibiting "the use of unapproved Materials" (¶80), and disciplining any employees who violated these policies (¶¶111-113, 172, 405).

568. The record demonstrates that the Board was entitled to rely on the FDA's review of all of Purdue's marketing materials. Under federal law, pharmaceutical companies are required to send the FDA all of their promotional materials "at the time of initial dissemination" or "initial publication." *See* 21 C.F.R. § 314.81(b)(3)(i). The FDA issues a "Warning Letter" or an "Untitled Letter" if it determines that any particular piece is not fair and balanced, or

contains inaccurate, misleading, or unsupported claims.[786] There is no evidence that Purdue received a single Warning or Untitled Letter from the FDA in connection with OxyContin during the Relevant Period.

569. Those Non-Estate Claims that require a showing that the Former Directors did not act in good faith or were negligent, grossly negligent, reckless, or acted with actual intent to deceive face a substantial risk of failure.

B. <u>Marketing Claims Are Likely to Fail for Lack of Personal Participation</u>

570. A director cannot be held liable for torts committed by his or her corporation unless s/he personally participated in the wrongdoing.[787]

571. The Court concludes that the Non-Estate Claims face a substantial risk of failure due to the inability to satisfy the personal participation requirement.

1. <u>Evidence of Non-Participation</u>

572. During the Relevant Period, the only role any Former Director had at Purdue was as a PPI director. ¶256.

573. The Former Directors have presented substantial evidence that none of them wrote, edited, commented on, approved or uttered any marketing statement during the Relevant Period. ¶¶279-281.

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[786] *See* FDA Regulatory Procedures Manual, Chapter 4 – Advisory Actions (2019), *available at* https://www.fda.gov/media/71878/download.

[787] *See* 3A WILLIAM MEADE FLETCHER, CYCLOPEDIA OF THE LAW OF CORPORATIONS §1137 (2018). *See also, e.g.*, *Lloyd v. Moore*, 115 A.D.3d 1309, 1310 (4th Dep't 2014); *Bernstein v. Starrett City, Inc.*, 303 A.D.2d 530, 532 (2d Dep't 2003); *Wesolek v. Jumping Cow Enters., Inc.*, 51 A.D.3d 1376, 1379 (4th Dep't 2008). Because personal participation is required for liability to attach to a corporate officer, "personal liability cannot be imposed on a corporate officer for nonfeasance, *i.e.*, a failure to act." *Peguero v. 601 Realty Corp.*, 58 A.D.3d 556, 559 (1st Dep't 2009); *see also Pomerance v. McGrath*, 143 A.D.3d 443, 447 (1st Dep't 2016); *MLM LLC v. Karamouzis*, 2 A.D.2d 161, 161-62 (1st Dep't 2003).

574. The Former Directors have presented substantial evidence that no marketing material was even submitted to the Board for approval. ¶¶280-82.

575. The Former Directors have presented substantial evidence that no marketing materials were changed or adopted because of a Board decision or the input of a Former Director. ¶282; *see also* ¶¶286, 289; JX-1989 (D. Sackler Dep. Tr.) at 245:6-17.

576. Some Claims rest on the argument that the Former Directors "micromanaged" Purdue, and extrapolate from this that they must have been involved in marketing. These general arguments of micromanagement do not support a conclusion that the Former Directors personally participated in decisions about the marketing of Purdue because none of these examples of alleged micromanagement concern marketing. ¶¶276-359. The documents cited in support of the micromanagement inference are (i) mischaracterized, (ii) irrelevant and/or (iii) decades old and relate to released conduct. *Id.*

577. The Court concludes that the Former Directors did not personally participate in Purdue's marketing during the Relevant Period.

578. The Former Directors did not engage in misconduct by relying on McKinsey & Co. McKinsey is "an internationally respected consulting firm"[788] on whom the Former Directors were entitled to rely under N.Y. B.C.L. §717(a)(1) & (2). The record does not suggest that there is anything about the McKinsey advice received by the Former Directors that makes their reliance on it unreasonable. ¶¶301-329.

579. The evidence presented indicates that the Former Directors made decisions predicated on the understanding that PPLP had a comprehensive compliance system in place

[788] *Samaritan Inns*, 1995 WL 405710; *see also, e.g.*, *Mercier*, 929 A.2d at 799 ("the respected firm of McKinsey & Co").

and was operating in compliance with law. That understanding was reasonable, based on detailed compliance reports they received every quarter during the Relevant Period, among other things. *See* ¶¶121-43.

2. Claims That Purdue's Post-2007 Marketing Was Deceptive Face Substantial Factual and Legal Hurdles

580. Deceptive marketing claims are also likely to fail for lack of proof that Purdue's post-2007 marketing was deceptive.

581. The record indicates that the federal government did not allege, in the 2020 Guilty Plea or Civil Settlement Agreement, that Purdue's Post-2007 marketing was deceptive.

582. The record reflects that the twelve key misrepresentations alleged against Purdue either were not made during the Relevant Period or are not deceptive. ¶¶363-418. Rather, the record shows that Purdue sought to persuade HCPs to prescribe its opioids over competitors' when medically appropriate. ¶360.

C. Negligent Diversion Claims Are Likely to Fail for Lack of Personal Participation

583. The Former Directors have presented substantial evidence that they did not personally participate in the administration or implementation of Purdue's anti-diversion activities and did not take any steps to undermine them.

584. The evidence presented indicates that the Board responsibly monitored management's anti-diversion efforts based on the information provided to it (¶¶143, 197-251).

585. Detailed compliance and other reports received by the Board confirmed that Purdue was implementing and monitoring its anti-diversion programs, including the ADD Program, which was designed to prevent promotion to HCPs where there was a concern about abuse or diversion. *See, e.g.*, ¶¶143, 146-148, 208-233.

586. The Board authorized the expenditure of more than $1 billion on additional anti-diversion efforts, including the development of ADF OxyContin. ¶145.

587. The record evidence therefore shows that the Former Directors acted in good faith, on the understanding that Purdue had in place extensive programs to address and reduce abuse and diversion.

588. Claims against the Former Directors based on Purdue's allegedly inadequate anti-diversion efforts are therefore likely to fail.

D. <u>The Public Nuisance Claims against the Former Directors Are Likely to Fail</u>

1. <u>The Public Nuisance Claims Are Likely to Fail as a Matter of Law</u>

589. The public nuisance doctrine does not extend to claims about the distribution of FDA-approved medicines. Several trial courts have expressly rejected public nuisance claims against Purdue and manufacturers or distributors,[789] and no appellate court has upheld this Claim.

590. Public nuisance law has traditionally been confined to claims regarding the use of property—not the sale and distribution of products, and especially not of an FDA-approved medicine. Appellate courts across the nation have rejected attempts like those by Claimants to reframe product liability claims as public nuisance claims.[790]

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789 *State ex rel. Jennings v. Purdue Pharma L.P.*, 2019 WL 446382, at *12-13 (Del. Super. Ct. Feb. 4, 2019); *State of North Dakota*, 2019 WL 2245743, at *11-13; *City of Everett v. Purdue Pharma L.P.*, 2017 WL 4236062, at *9 (W.D. Wash. Sept. 25, 2017); *Grewal v. Purdue Pharma L.P.*, 2018 WL 4829660, at *18 (N.J. Super. Ct. Oct. 2, 2018); JX-2475 (Transcript of Bench Decision) at 23:23-24:4, *State ex rel. Ravnsborg v. Purdue Pharma L.P.*, No. 32CIV18-000065 (S.D. Cir. Ct., Hughes Cnty. Jan. 13, 2021).

790 *See, e.g.*, *Camden Cnty. Bd. of Chosen Freeholders v. Beretta, U.S.A. Corp*, 273 F.3d 536, 540 (3d Cir. 2001) ("[N]o New Jersey court has ever allowed a public nuisance claim to proceed against manufacturers for lawful products that are lawfully placed in the stream of commerce."); *Tioga*

591. Public nuisance is not a catchall tort. Allowing product liability claims to proceed under the guise of public nuisance would "open the courthouse doors to a flood of limitless, similar theories of public nuisance … against a wide and varied array of other commercial and manufacturing enterprises and activities."[791]

592. The nuisance Claims against the Former Directors will have difficulty satisfying basic elements of public nuisance, which require interference with a public right[792] and control of the instrumentality causing the harm.[793]

593. First, the alleged right of individuals not to be subjected to the risk of abuse and addiction from FDA-approved opioids when they are not medically necessary is likely to be held a private, not public, right.[794] Whether a right is public "depends on the nature of the interest affected by the defendant's conduct" and "is not simply a matter of tallying the number

Pub. Sch. Dist. No. 15 v. U.S. Gypsum Co., 984 F.2d 915, 920 (8th Cir. 1993) (rejecting public nuisance claim based on asbestos); *Rhode Island v. Lead Indus., Inc.*, 951 A.2d 428, 456 (R.I. 2008) ("The law of public nuisance never before has been applied to products, however harmful."); *In re Lead Paint Litig.*, 924 A.2d 484, 505 (N.J. 2007) ("were we to permit these complaints to proceed, we would stretch the concept of public nuisance far beyond recognition and would create a new and entirely unbounded tort antithetical to the meaning and inherent theoretical limitations of the tort of public nuisance"); *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099, 1116 (Ill. 2004) ("there is no authority for the unprecedented expansion of the concept of public rights to encompass the right asserted by plaintiffs").

791 *People ex rel. Spitzer v. Sturm, Ruger & Co.*, 309 A.D.2d 91, 96 (1st Dep't 2003). *See also Tioga Pub. Sch. Dist. No. 15*, 984 F.2d at 920.

792 *See, e.g.*, RESTATEMENT (SECOND) OF TORTS § 821B(1); *Lead Indus.*, 951 A.2d at 453.

793 *See, e.g.*, *Lead Indus.*, 951 A.2d at 449; *Cofield v. Lead Indus. Ass'n, Inc.*, 2000 WL 34292681, at *7 (D. Md. Aug. 17, 2000).

794 *See, e.g.*, *Lead Indus.*, 951 A.2d at 448 ("Products generally are purchased and used by individual consumers, and any harm they cause—even if the use of the product is widespread and the manufacturer's ... conduct is unreasonable—is not an actionable violation of a public right.").

of people affected."[795] Courts have rejected public nuisance claims arising from widespread public health issues related to lead paint, firearms, and other products.[796]

594. Second, in many jurisdictions, an essential element of public nuisance is control over the instrumentality at the time of the harm.[797] That requirement is likely to be an unsurmountable obstacle for Claimants under the law of those jurisdictions. Purdue did not have control over the alleged public nuisance at the time of harm because it ceded control over its medications when they were sold to distributors.

2. <u>The Public Nuisance Claims Are Factually Unsupported</u>

595. The public nuisance claims are likely to fail because there is no evidence either that the Former Directors (i) oversaw wrongful conduct by Purdue that created a public nuisance, or (ii) personally participated in it.

596. To the extent the wrongful conduct alleged is misleading marketing by Purdue, there is no evidence before the Court establishing that Purdue's marketing was misleading during the Relevant Period. *Supra* ¶¶362-414.

597. Even if Purdue's marketing was misleading during the Relevant Period, the record indicates that Former Directors did not personally participate in Purdue marketing. *Supra* §VI.

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[795] *Rhodes v. E.I. du Pont de Nemours & Co.*, 636 F.3d 88, 96 (4th Cir. 2011).

[796] *See, e.g.*, *Lead Indus.*, 951 A.2d at 436 (lead paint); *City of Chicago*, 821 N.E.2d at 1116 (firearms).

[797] *See, e.g.*, *Jennings*, 2019 WL 446382, at *13; JX-2475 (Transcript of Bench Decision at 24:1-3, *State ex rel. Ravnsborg v. Purdue Pharma L.P.*, No. 32CIV18-000065 (S.D. Cir. Ct., Hughes Cnty. Jan. 13, 2021); *Lead Indus.*, 951 A.2d at 454.

598. The personal participation requirement is not satisfied merely because an individual sat on the board of a company that allegedly contributed to a public nuisance.[798] Nor is the Board's receipt of general information about Purdue's business activities a viable basis for public nuisance liability.[799]

E. Claimants Will Likely Be Unable to Show A Proximate Causal Link between the Former Directors' Conduct and Their Alleged Injuries

599. The Former Directors have presented numerous factual and legal reasons to believe that the Non-Estate Claims are likely to fail for the independent reason that Claimants cannot establish a causal chain that satisfies either but-for or proximate causation.

600. For damages to be recoverable, there must be evidence that Purdue's allegedly deceptive marketing or diversion control failures are both the cause-in-fact and the proximate cause of the claimed injuries.[800]

601. The Non-Estate Claims face numerous causation problems that Claimants are unlikely to overcome.

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[798] *Estate of Goldberg v. Goss-Jewett Co., Inc.*, 2019 WL 4221398, at *3-4 (C.D. Cal. June 4, 2019).

[799] *Id.*; *Sahu v. Union Carbide Corp.*, 2012 WL 2422757, at *5 (S.D.N.Y. June 26, 2012), *aff'd*, 528 F. App'x 96 (2d Cir. 2013).

[800] *See, e.g.*, *Small v. Lorillard Tobacco Co.*, 252 A.D.2d 1, 15-16 (1st Dep't 1998), *aff'd*, 94 N.Y.2d 43 (1999) (N.Y. GEN. BUS. LAW §§349, 350 and common-law fraud claims); *Bilinski v. Keith Haring Found., Inc.*, 96 F. Supp. 3d 35, 52 (S.D.N.Y. 2015), *aff'd in relevant part*, 632 F. App'x 637 (2d Cir. 2015) (unjust enrichment); *Nealy v. U.S. Surgical Corp.*, 587 F. Supp. 2d 579, 583–85, 588 (S.D.N.Y. 2008) (negligence). *See also Bank of Am. Corp. v. City of Miami*, 137 S. Ct. 1296, 1306 (2017) (the inability to demonstrate "some direct relation between the injury asserted and the injurious conduct alleged" "generally bars suits for alleged harm that is too remote from the defendant's … conduct").

1. Causation Was Found Lacking in Litigation against Purdue Based on Misconduct Admitted in the 2007 Guilty Plea

602. Many personal injury cases were brought against Purdue based on the conduct that was the subject of the 2007 Guilty Plea. But courts found there was no evidence that Purdue's misconduct caused HCPs to make prescribing decisions they otherwise would not have made.[801] For this and other reasons (including intentional misuse), courts consistently found causation lacking.[802]

2. Claimants Cannot Show That Purdue's Marketing Statements Caused Doctors to Write Medically Unnecessary Prescriptions

603. The linchpin of Claimants' marketing claims is that deceptive marketing by Purdue caused doctors to write medically unnecessary opioid prescriptions. But there is no evidence in the record connecting any of Purdue's alleged misconduct to even a single improper prescription, and there is substantial reason to doubt that such evidence can be adduced.

604. Significant contrary evidence has been adduced, including that HCPs write prescriptions for many reasons other than marketing, such as the FDA-approved label,

[801] *See,e.g.*, *United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569, 575 (W.D. Va. 2007) (accepting guilty plea; recognizing that, "[a]s to any individuals injured by the use of OxyContin, the difficulties of establishing causation, as demonstrated by the numerous civil suits that have been filed" and that "Courts have consistently found that despite extensive discovery, plaintiffs were unable to show that Purdue's misbranding proximately caused their injuries.").

[802] *See, e.g.*, *Bodie v. Purdue Pharma Co.*, 236 F. App'x 511 (11th Cir. 2007); *Foister v. Purdue Pharma, L.P.*, 295 F. Supp. 2d 693 (E.D. Ky. 2003); *Labzda v. Purdue Pharma, L.P.*, 292 F. Supp. 2d 1346 (S.D. Fla. 2003); *Koenig v. Purdue Pharma Co.*, 435 F. Supp. 2d 551 (N.D. Tex. 2006); *McCauley v. Purdue Pharma, L.P.*, 331 F. Supp. 2d 449 (W.D. Va. 2004); *Boysaw v. Purdue Pharma*, 2008 WL 4452650 (W.D. Va. Sept. 30, 2008), *aff'd*, 320 F. App'x 178 (4th Cir. 2009); *Timmons v. Purdue Pharma Co.*, 2006 WL 263602, (M.D. Fla. Feb. 2, 2006); *Cornelius v. Cain*, 2004 WL 48102 (Fl. Cir. Ct., Broward Cnty. Jan. 5, 2004); *Harris v. Purdue Pharma, L.P.*, 218 F.R.D. 590 (S.D. Ohio 2003).

education and experience, individual patient characteristics, other medications being taken by the patient, availability of alternative medications, and insurance coverage.[803]

605. The record reflects that HCPs decide whether an opioid is necessary and appropriate, as well as whether the patient is likely to abuse or divert the medication. This involves a complex professional assessment in light of the physical and mental condition of the patient, the patient's symptoms, whether the patient has a history of substance abuse or misuse, and other factors.[804]

606. Purdue has never marketed directly to patients.

607. The Former Directors do not diagnose, treat or prescribe to patients. That is done exclusively by licensed, registered medical professionals in the exercise of their medical judgment.[805] Purdue and its directors have no ability to review or second-guess the validity of a prescription written by a licensed HCP.

608. Under the Learned Intermediary Doctrine, prescribing physicians intervene as "the 'informed intermediary' between the manufacturer and the patient" to make decisions about medical treatment, "evaluating the patient's needs, assessing the risks and benefits of

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[803] *See, e.g.*, *Travelers Indem. Co. v. Cephalon, Inc.*, 620 F. App'x 82, 87 (3d Cir. 2015) ("Allegations that physicians attended presentations and interacted with Cephalon sales representatives do not sufficiently demonstrate that these interactions *caused* the physicians to write the prescriptions at issue.") (emphasis in original).

[804] *See, e.g.*, DEA Policy Statement, *Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. 52,716 at 52,723, 52719-20.

[805] *See* 21 C.F.R. § 1306.04(a); N.Y. PUB. HEALTH LAW § 3332(1); 10 N.Y.C.R.R. § 80.64.

available drugs, and prescribing and supervising their use."[806] Numerous courts have dismissed claims against drug manufacturers based on this doctrine.[807]

609. The record reflects that pharmaceutical marketing is only one of many informational resources used by physicians in independently assessing the appropriateness of Purdue's opioid products for a patient, and professional literature indicates that it is seldom—if ever—the most important. The literature reflects that physicians are often skeptical of information provided by pharmaceutical sales representatives.[808] The many other sources of information available to HCPs include FDA-approved labeling, peer-reviewed medical journals, continuing medical education, and literature required under the FDA-approved Risk Evaluation and Mitigation Strategies that communicate the risks of opioids to prescribers.

3. OxyContin Has Always Had a Small Market Share, and It Has Been in Decline for over 15 Years

610. The record reflects that OxyContin prescriptions have never represented more than a small fraction of prescriptions for opioid analgesics in the United States. OxyContin's

[806] *See, e.g.*, *Glucksman v. Halsey Drug Co.*, 160 A.D.2d 305, 307 (1st Dep't 1990); *see also Wolfgruber v. Upjohn Co.*, 72 A.D.2d 59, 61 (4th Dep't 1979), *aff'd*, 52 N.Y.2d 768 (1980); *Martin v. Hacker*, 83 N.Y.2d 1, 9 (1993).

[807] See, e.g., *Bodie*, 236 F. App'x at 521; *Ironworkers Local Union No. 68 v. AstraZeneca Pharm. LP*, 585 F. Supp. 2d 1339, 1344 (M.D. Fla. 2008); *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 873 F.3d 574, 576-77 (7th Cir. 2017); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, 2010 WL 3119499, at *7-9 (S.D. Ill. Aug 5, 2010).

[808] *See, e.g.*, W. McKinney et al., *Attitudes of Internal Medicine Faculty and Residents Toward Professional Interaction with Pharmaceutical Sales Representatives*, 264 JAMA 1693 (1990); Marilyn Peay & Edmund Peay, Patterns of Preference for Information Sources in the Adoption of New Drugs by Specialists, 31 SOC. SCI. & MED. 467 (1990).

share of the opioid prescription market reached a peak of 4% in 2003 and its market share has been below 2% in recent years.[809]

611. Prescriptions for extended-release opioid prescriptions (including OxyContin) have represented "a very small and decreasing fraction" of opioid prescriptions since 2010.[810] Even if measured in terms of MMEs, the total number of MMEs sold in all ER opioid formulations has never equaled the total MMEs sold by manufacturers of immediate release opioids,[811] which dominate the market for prescription opioids.[812]

4. Widespread Confusion between OxyContin and Oxycodone

612. The evidence presented indicates that confusion between OxyContin and immediate-release oxycodone, which is far more prevalent, has been widespread for years. For example, a 2010 ABC news article discussing oxycodone was given the misleading title "OxyContin Riskier Than Other Pills, Study Finds," even though the expert quotations that follow all deal with oxycodone.[813] The same confusion has been manifest in Congressional

[809] *See* Debtors' Informational Brief at 22.

[810] JX-2473 (1/21/20 Letter from Janet Woodcock, Director for FDA, to Senator Maggie Hassan) *available at* https://www.hassan.senate.gov/imo/media/doc/FDA%20RESPONSE%20HASSAN%201.21.20.pdf.

[811] *See* U.S. FOOD & DRUG ADMINISTRATION, FDA ANALYSIS OF LONG-TERM TRENDS IN PRESCRIPTION OPIOID ANALGESIC PRODUCTS: QUANTITY, SALES, AND PRICE TRENDS (Mar. 1, 2018), https://www.fda.gov/media/111695/download at PDF page 2.

[812] U.S. FOOD & DRUG ADMINISTRATION, FDA BRIEFING DOCUMENT, JOINT MEETING OF THE DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE AND ANESTHETIC AND ANALGESIC DRUG PRODUCTS ADVISORY COMMITTEE, OXYCONTIN ABUSE DETERRENT FORMULATION (ADF) 10 (2020), PDF page 98, https://www.fda.gov/media/141914/download .

[813] Mikaela Conley, *Some Painkillers Safer Than Others, Study Finds*, ABC NEWS (Dec. 13, 2010), https://abcnews.go.com/Health/opioids-increase-risk-problems/story?id=12383100.

hearings.[814] A key reason for the confusion, apart from the similarity of names, is that the pills—OxyContin and oxycodone—frequently look identical.[815]

5. <u>OxyContin Did Not Trigger the Opioid Crisis</u>

613. The record before the Court reflects that the modern opioid crisis took root long before the introduction of OxyContin in 1996. Data from the CDC show that opioid-related deaths were all rising before the launch of OxyContin in 1996, and continued to rise as OxyContin prescriptions and market share fell.[816]

6. <u>For a Decade, the Opioid Crisis Has Been Driven by Illicit Drugs</u>

614. The record reflects that, as the AMA recently observed: "The nation no longer has a prescription opioid-driven epidemic."[817] The CDC has described the opioid crisis as having three waves: a rise in prescription opioid deaths beginning in 2010, followed by a rise in

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[814] Commerce, Justice, Science, and Related Agencies Appropriations for 2012: Hearing Before a Subcomm. of the H. Comm. on Appropriations, 107th Cong. (2012), available at https://www.govinfo.gov/content/pkg/CHRG-112hhrg67259/html/CHRG-112hhrg67259.htm.

[815] *See* JX-2375 (2015 pill card) (PPLPC020000725747) at -777. *See also* JX-2404 (2016 pill card) (PPLPC017000522734) at -774; (2017 pill card): SUBSTANCE ABUSE AND MENTAL HEALTH SERVICE ADMINISTRATION CENTER FOR BEHAVIOR HEALTH STATICS AND QUALITY, 2017 NATIONAL SURVEY ON DRUG USE AND HEALTH: PRESCRIPTION DRUG IMAGES FOR THE 2017 QUESTIONNAIRE 4-5, *available at* https://www.samhsa.gov/data/sites/default/files/NSDUH-PillImages-2017.pdf.

[816] John Kamp, *Overdose Deaths Likely to Fall for the First Time Since 1990*, WALL ST. J., June 26, 2019 https://www.wsj.com/articles/overdose-deaths-likely-to-fall-for-first-time-since-1990-11561541406.

[817] June 16, 2020 Letter from AMA to CDC, https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2020-6-16-Letter-to-Dowell-re-Opioid-Rx-Guideline.pdf.

heroin overdose deaths, followed most recently by a rise in deaths from misuse of synthetic opioids like illicit fentanyl beginning in 2013.[818]

615. Overdose deaths involving prescription opioids alone (as opposed to in combination with other substances) peaked a decade ago, in 2011.[819]

616. According to the CDC, between 2013 and 2016, fentanyl-related deaths approximately doubled each year.[820] The Massachusetts Department of Health reports that, among 903 opioid-related overdose deaths in 2019 where a toxicology screen was available, 838—or 93%—tested positive for fentanyl.[821]

617. The Non-Estate Claims will likely be found to lack causation as a matter of law to the extent they seek to hold Purdue and the Former Directors liable for purported injuries from illicit drugs or for illegally obtained opioid medications.

618. Based on the record before the Court, there is no evidence causally linking manufacturers' marketing of prescription opioids to the rise of heroin or illicit fentanyl, or to counterfeit pills, or the trafficking of illegally obtained prescription drugs by pill mills and other criminal enterprises.

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818 CDC, 3 WAVES OF THE RISE IN OPIOID OVERDOSE DEATHS, https://www.cdc.gov/drugoverdose/images/epidemic/3WavesOfTheRiseInOpioidOverdoseDeaths.png (last visited Feb. 12, 2021).

819 *Available at* https://web.archive.org/web/20210127234432/https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates.

820 *See* Merianne Rose Spencer et al., *Drug Overdose Deaths Involving Fentanyl 2011-2016*, 68 NAT'L VITAL STAT. REP. 1, 3 (Mar. 21, 2019), https://www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_03-508.pdf.

821 *See* MASS. DEP'T OF PUB. HEALTH, *Data Brief: Opioid-Related Overdose Deaths Among Massachusetts Residents* 2 (Nov. 2019), https://www.mass.gov/files/documents/2019/11/25/Opioid-related-Overdose-Deaths-among-MA-Residents-November-2019.pdf.

619. As the FDA's National Institute on Drug Abuse has noted, "[a]ccording to general population data from the National Survey on Drug Use and Health, less than 4 percent of people who had abused prescription opioids started using heroin within 5 years."[822] This indicates that any alleged "transitioning" from prescription opioid abuse to heroin occurs, at most, in a very small subset of users. A recent study published in the *Journal of Addiction Medicine* found that there is no relationship between long-term or high-dose prescription opioid use and heroin initiation.[823]

620. Nor is there evidence before the Court to support the allegation by some Claimants that introduction of ADF OxyContin in 2010 fueled an epidemic of heroin and illicit fentanyl abuse continuing over a decade later. Past cycles of illicit drug abuse in the U.S. are well-documented, including a heroin spike in the 1960s and 1970s followed by a cocaine spike in the 1980s and a methamphetamine spike in the 1990s. Heroin abuse has been increasing since at least 2007, before the introduction of ADF OxyContin.[824]

621. A recent study published in the journal *Addictive Behaviors* found based on 2005-2014 National Survey on Drug Use and Health data that "the reformulation of OxyContin

[822] JX-2188 (NIDA, PRESCRIPTION OPIOIDS AND HEROIN RESEARCH REPORT (rev. Jan. 2018), *available at* https://www.drugabuse.gov/publications/research-reports/prescription-opioids-heroin/heroin-use-rare-in-prescription-drug-users) at 5.

[823] Daniel M. Hartung, et al., *Patterns of Prescription Opioid Use Prior to Self-reported Heroin Initiation*, 15 J. ADDICTION MED. 130, 131-32 (March/April 2021).

[824] *See, e.g.*, Wilson M. Compton, et al., *Relationship between Nonmedical Prescription-Opioid Use and Heroin Use,* 37 NEW ENG. J. MED. 154, 157 (Jan. 14, 2016).

appears to have reduced prescription pain reliever misuse without contributing to relatively greater new heroin use among those who misused OxyContin prior to reformulation."[825]

622. The FDA has concluded that the "[c]omplex mixture of data limitations of data, concurrent interventions, and secular trends make it difficult to determine the exact contribution of OxyContin's reformulation to U.S. opioid mortality trends."[826]

7. Intervening Criminal Conduct Breaks the Causal Chain

623. The Non-Estate Claims are likely to fail for lack of causation because any causal connection is broken by criminal conduct over which Purdue and the Former Directors exercise no control. Such conduct includes HCPs' unlawful prescriptions, patients' decisions to unlawfully divert opioids prescribed to others, other criminal acts to obtain opioids, and accidental or intentional misuse or abuse of opioids.[827]

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[825] Carolyn Wolff et al., *The impact of the abuse-deterrent reformulation of extended-release OxyContin on prescription pain reliever misuse and heroin initiation*, ADDICTIVE BEHAVIORS 105 (2020), available at https://digitalcommons.unl.edu/usfda/51/, at 1. *See also* Shiyu Zhang & Daniel Guth, *The OxyContin Reformulation Revisited: New Evidence From Improved Definitions of Markets and Substitutes* at 28 (Jan. 28, 2021), available at https://arxiv.org/pdf/2101.01128.pdf.

[826] FDA, LITERATURE REVIEW: IMPACT OF REFORMULATED OXYCONTIN ON ABUSE AND OPIOID-RELATED MORBIDITY AND MORTALITY, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and Anesthetic and Analgesic Drug Products Advisory Committee, OxyContin Abuse Deterrent Formulation (ADF) at 32 (2020), *available at* https://www.fda.gov/media/141974/download. *See also id. at* FDA, FDA SUMMARY OF POSTMARKETING FINDINGS ON OXYCONTIN ADF EFFECTIVENESS AND PUBLIC HEALTH IMPACT, *available at* https://www.fda.gov/media/141974/download at 14 (pdf p. 53).

[827] *See, e.g.*, *Floyd v. Feygin*, 2018 WL 6528728, at *16 (Sup. Ct. Kings Cnty. Dec. 6, 2018) ("The operation of the 'pill mill' was an intervening act which was of an extraordinary and criminal nature so as to break any causal nexus between any reporting requirement on the part of Actavis and plaintiff's addiction to Oxycodone.").

8. Addiction and Abuse Rarely Stem from Medically-Prescribed Opioid Use

624. The record reflects that the FDA and independent studies have determined that that a patient's risk of addiction from taking an opioid as prescribed by his or her doctor is low. *See* ¶¶15, 371. Prior use of prescribed OxyContin is very rare among patients treated for opioid addiction.[828]

625. The evidence presented to the Court indicates that most people who abuse opioids obtain them illicitly from friends, relatives, or street level drug dealers, and not from the HCPs to whom Purdue's marketing was directed—HCPs prescribing opioids for legitimate use. The National Survey on Drug Use and Health conducted by SAMHSA in 2008 found that only 7% of people who abuse OxyContin obtained their drugs from a doctor:[829] Between 2013 and 2014, more than 65% of abused prescription opioids were obtained from a friend or relative.[830]

[828] *See, e.g.*, Deni Carise, et al., *Prescription OxyContin Abuse Among Patients Entering Addiction Treatment*, 164 AM. J. PSYCHIATRY 1750, 1750 (2007), https://ajp.psychiatryonline.org/doi/pdf/10.1176/appi.ajp.2007.07050252 (finding only 5% of 27,816 subjects admitted to 157 addiction treatment programs reported prior use of OxyContin—and 78% of those users also reported that OxyContin had not been prescribed to them for any medical reason).

[829] JX-2290 (July 22-23, 2010 Joint Meeting of the FDA Anesthetic and Life Support Drugs Advisory Committee and Drug Safety and Risk Mgmt. Advisory Committee, *Risk Evaluation and Mitigation Strategies (REMS) for Extended-Release and Long-Acting Opioid Analgesics*) (PPLP003366082, at -089).

[830] Rachel N. Lipari & Arthur Hughes, *How People Obtain the Prescription Pain Relievers They Misuse*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (Jan. 12, 2017), https://www.ncbi.nlm.nih.gov/books/NBK424785/pdf/Bookshelf_NBK424785.pdf.

9. Many Factors Cause the Alleged Injuries

626. The record reflects that opioid crisis is a multifaceted problem with no one actor or product as the cause.[831] These include individual patient factors associated with opioid overdose (*e.g.*, mental health diagnoses, family history of substance abuse);[832] rogue HCPs overprescribing opioids to patients with no legitimate need;[833] deceptive, doctor-shopping patients;[834] patients not taking drugs as prescribed, despite explicit and detailed warnings;[835]

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[831] *See* MASS. DEP'T OF PUB. HEALTH, The Massachusetts Opioid Epidemic: A Data Visualization of Findings From the Chapter 55 Report, at 7, https://chapter55.digital.mass.gov/ (last visited Feb. 13, 2021).

[832] JX-2473 (2020 FDA Letter to Senator Maggie Hassan), *available at* https://www.hassan.senate.gov/imo/media/doc/FDA%20RESPONSE%20HASSAN%201.21.20.pdf; *see also* Joanne Neale, *Suicidal Intent in Non-fatal Illicit Drug Overdose*, 95 ADDICTION 85, 91-92 (2000), *available at* https://ur.booksc.eu/book/5081629/af802c (select "Download (pdf, 124 KB)"); *Criminal Justice DrugFacts*, NAT'L INST. ON DRUG ABUSE (June 2020) https://www.drugabuse.gov/publications/drugfacts/criminal-justice#ref.

[833] *See* Kelly K. Dineen, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42 AM. J. L. MED. 7 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5494184/.

[834] *See* Douglas C. McDonald & Kenneth E. Carlson, *Estimating the Prevalence of Opioid Diversion by "Doctor Shoppers" in the United States*, 8(7) PLOS ONE e69241 (2013); Randy A. Sansone, MD & Lori A. Sansone, *Doctor Shopping: A Phenomenon of Many Themes*, 9 INNOVATIONS CLINICAL NEUROSCIENCE 42, 42 (2012).

[835] *See* JX-2104 (2007 Label) (PPLPC031000441510); *FDA Approves Abuse Deterrent Labelling for Reformulated OxyContin*, FDA (Apr. 16, 2013), https://web.archive.org/web/20130419012709/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm348252.htm; 2018 Label at 4, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022272s039lbl.pdf; JX-2114 (Apr. 16, 2013 OxyContin FDA Label) (PPLPC003000060503).

diversion from friends and relatives;[836] and socioeconomic factors such as despair, loss of purpose, and dissolution of communities.[837]

10. Conflation of All Manufacturers' Opioids

627. To establish causation, it is necessary to prove that the allegedly wrongful conduct of Purdue—and then the Former Directors—was a substantial factor in bringing about the alleged injuries.

628. Prescription opioid manufacturers' products are not interchangeable. They vary widely in terms of their approved indications, formulation, and potency. They are distinctly labeled. OxyContin's extended-release abuse-deterrent formulation distinguished it from many other manufacturers' opioids, and OxyContin competed with other ER formulations. The manufacturers are competitors that employed different marketing strategies over different periods for their different opioid products.

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836 *See* Rachel N. Lipari & Arthur Hughes, *How People Obtain the Prescription Pain Relievers They Misuse*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (Jan. 12, 2017), https://www.ncbi.nlm.nih.gov/books/NBK424785/pdf/Bookshelf_NBK424785.pdf; J.A. Inciardi et al., *Prescription Opioid Abuse and Diversion in an Urban Community: The Results of an Ultrarapid Assessment*, 10 PAIN MED. 537 (2009); U.S. DEP'T HEALTH & HUMAN RESOURCES, RESULTS FROM THE 2013 NATIONAL SURVEY ON DRUG USE AND HEALTH: SUMMARY OF FINDINGS 33, https://www.samhsa.gov/data/sites/default/files/NSDUHresultsPDFWHTML2013/Web/NSDUHresults2013.pdf; STERICYCLE, UNUSED PRESCRIPTIONS & THE OPIOID EPIDEMIC 3 (March 2019), https://www.stericycle.com/getattachment/Knowledge-Center/KC/Original-Research/2019-Drug-Takeback-Survey-Unused-Prescriptions-an/2019-Unused-Prescriptions-and-The-Opioid-Epidemic-Study.pdf.aspx?lang=en-US; Johns Hopkins Bloomberg School of Public Health & Clinton Foundation Clinton Health Matters Initiative, THE OPIOID EPIDEMIC: FROM EVIDENCE TO IMPACT 5 (Oct. 2017).

837 *See, e.g.*, Hawre Jalal, et al., *Changing dynamics of the drug overdose epidemic in the United States from 1979 through 2016*, 361 SCIENCE 1218 (Sep. 21, 2018); NAT'L INST. ON MINORITY HEALTH AND HEALTH DISPARITIES, The Drug Overdose Epidemic Affects All Communities, NIH.GOV (Oct. 25, 2019), https://nimhd.nih.gov/news-events/features/community-health/overdose-epidemic.html.

629. There is no evidence before the Court attempting to differentiate and attribute any particular bad outcome to any particular opioid.

11. Continuing Reimbursement of Opioid Prescriptions

630. To the extent that any payor continues to approve reimbursement of patients for opioid prescriptions for OxyContin, that is likely to preclude any claim that Purdue's alleged misrepresentations were material to decisions to authorize reimbursement.[838]

12. Claims for Abatement Costs Are Otherwise Deficient

631. Decades of future abatement costs are a principal alleged harm. However, there is no reliable way of knowing what, if any, expenses will be incurred 5, 10 or 20 years from now, or what will have caused those expenses.

632. The only court that has ordered an abatement remedy in connection with prescription opioids—the Oklahoma trial court, in a decision against Johnson & Johnson that is on appeal—rejected a twenty-year abatement plan as lacking sufficient supporting evidence.[839]

633. Nor would this Court have the resources to oversee and enforce a complex, multi-jurisdictional abatement plan.

[838] *See Teamsters Local 237 Welfare Fund v. AstraZeneca Pharm. LP*, 136 A.3d 688, 696 (Del. 2016) (analyzing New York law) ("[Third-party payors] who continue to pay or reimburse for [a medication], while claiming they were harmed by allegedly false advertising, are neither 'victims' of the allegedly false advertising nor were they injured by reason of or as a result of it. They were injured by their own conduct."); *accord State of North Dakota*, 2019 WL 2245743, at *9, ¶51.

[839] *State of Oklahoma v. Purdue Pharma, L.P.*, 2019 WL 9241510, at *15 (Okla. Dist. Ct. Nov. 15, 2019).

634. Further, in some jurisdictions, abatement costs as well as historical costs would likely be held to run afoul of the municipal cost recovery rule, "under which public expenditures made in the performance of governmental functions are not recoverable in tort."[840]

635. The economic loss doctrine is likely to independently bar recovery of abatement costs in several jurisdictions.[841] This doctrine bars recovery for expenses—like education costs, child welfare costs, criminal justice system costs, lost income and sales tax allegedly resulting from lower labor force participation—that relate only tangentially to opioid abuse because these damages are purely economic and involve no personal injury or harm to Claimants' property.

F. Federal Law Preempts Attacks on Marketing Consistent with the FDA-Approved Label

636. "When federal law forbids an action that state law requires, the state law is without effect."[842] State law is also preempted if it either "regulates conduct in a field that Congress intended the Federal Government to occupy exclusively," or "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[843]

637. Many of the Non-Estate Claims amount to disagreements with FDA-approved statements or deem FDA-approved disclosures insufficient, *see supra* ¶¶365-410. Those claims are likely barred by preemption.

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[840] *City of Chicago*, 821 N.E.2d at 1139; *see also City of Flagstaff v. Atchison, Topeka & Santa Fe Ry. Co.*, 719 F.2d 322, 323 (9th Cir. 1983) (Kennedy, J.); *District of Columbia v. Air Fla.*, 750 F.2d 1077, 1080 (D.C. Cir. 1984).

[841] *See, e.g.*, *Tyler v. Gibbons*, 857 N.E.2d 885, 888 (Ill. App. Ct. 2006) ("In Illinois, solely economic losses are generally not recoverable in tort actions.").

[842] *Mut. Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 486 (2013) (state law that makes it inherently tortious for drug manufacturer to sell FDA-approved medication is preempted).

[843] *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990).

1. Federal Law Preempts Claims Based on Statements in the Label

638. A state-law fraud claim is preempted if "the statements on which the fraud claim is premised depend[] on statements made to and approved by the FDA."[844] Only the FDA has the authority to sue for "false or misleading" statements in an FDA-approved label.[845] Non-FDA actions seeking relief for alleged misrepresentations in a label are barred because they improperly second-guess the FDA's determination that information on a label is true and accurate.

639. Here, Claimants' Non-Estate Claims fail to the extent they assert that statements contained in the FDA-approved label are deceptive. The record reflects that these include allegations that Purdue's marketing improperly advised HCPs that: (1) tapering OxyContin may be appropriate to address withdrawal; (2) OxyContin has no ceiling dose; (3) pseudoaddiction exists; and (4) one OxyContin pill provides a 12-hour dose. *Supra* ¶¶373-77, 384-94, 404-07.

2. Federal Law Preempts Alleged Failure to Warn Claims

640. Federal law preempts a state-law fraud claim based on statements contained in an FDA-approved label that the defendant could not have unilaterally removed through the so-called changes being effected ("**CBE**") process.

641. The CBE process allows a manufacturer to add to an FDA-approved label only "*newly acquired information*" that "reveal[s] risks of a different type or greater severity or frequency than previously included in submissions to the FDA." 21 C.F.R. § 314.70(c)(6)(iii);

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[844] *Utts v. Bristol–Myers Squibb Co.*, 251 F.Supp.3d 644, 680 (S.D.N.Y. 2017), *aff'd sub nom. Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699 (2d Cir. 2019); *see also Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228, 1234 (S.D. Fla. 2007).

[845] *Zimmerman v. Novartis Pharm. Corp*., 889 F. Supp. 2d 757, 769 (D. Md. 2012); *see also* 21 U.S.C. §§ 337(a), 372.

21 C.F.R. § 314.3(b). But the FDA has the authority to reject the label change. *See* 21 C.F.R. § 314.70(c)(6), (7). If a manufacturer wants to make a change to the FDA label that does not fall within the CBE regulation, the manufacturer must obtain FDA approval.[846]

642. State law can impose on a manufacturer a duty to change a drug label through the CBE regulation, but federal law preempts any claim that the manufacturer was required to make other changes to the label. *In re Celexa*, 779 F.3d at 41. To avoid preemption, a plaintiff must identify "a labeling deficiency that Defendants could have corrected using the CBE regulation." *Gibbons*, 919 F.3d at 708.

643. On April 5, 2010, the FDA approved Purdue's NDA for ADF OxyContin, and the new label did not include the warnings on which the Non-Estate Claims are based. The FDA's decision shows that the FDA concluded that the warnings Claimants contend should have been included were unnecessary based on the information available on April 5, 2010.[847]

644. Consequently, Claimants are likely to be barred from challenging the sufficiency of the OxyContin label's warnings based on evidence that was available on April 5, 2010. *See In re Celexa*, 779 F.3d at 41, 43.

645. There is no evidence of any information discovered after April 5, 2010, not previously considered by the FDA, that would have allowed Purdue to unilaterally change the OxyContin label to add the warnings. Studies that were available in 2010, when the FDA first approved the label for re-formulated OxyContin, are insufficient. So, too, are post-2010 studies, unless they reveal risks of a different type or greater severity or frequency than those included

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[846] *See In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779 F.3d 34, 40-41 (1st Cir. 2015).

[847] *See* 21 C.F.R. § 314.105(c) ("FDA will approve an NDA after it determines that the drug meets the statutory standards for safety and effectiveness … and labeling").

in Purdue's submissions to the FDA. There is no evidence of such studies, and information that was not "newly acquired" could not have served as a basis for Purdue to change its label.[848]

646. A number of Non-Estate Claims are also likely to fail because in 2013 the FDA explicitly rejected an attempt to add to the label the warnings that many of the Non-Estate Claims maintain should have been included in Purdue's marketing. The FDA rejected a petition that sought to add quantity and day limits to OxyContin prescriptions.[849] The FDA's rejection of that petition is "clear evidence" that the FDA would not have allowed Purdue to add those warnings to the label. *Gibbons*, 919 F.3d at 708. Non-Estate Claims that Purdue's marketing was deceptive because it did not include those warnings are therefore likely preempted.

G. Personal Jurisdiction over the Former Directors Is Lacking in Many of the Non-Bankruptcy Litigations

1. Supreme Court Personal Jurisdiction Jurisprudence Requires Substantial Suit-Related Contacts in the Forum

647. Personal jurisdiction may be asserted only over non-resident defendants who have substantial, personal, suit-related contacts with the forum state.[850]

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[848] *See Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 816 (7th Cir. 2018), *cert. denied*, 139 S. Ct. 2636 (2019); *Utts*, 226 F. Supp. 3d at 184; *Gibbons*, 919 F.3d at 708; *In re Celexa*, 779 F.3d at 43; *Patton v. Forest Labs., Inc.*, 2018 WL 5269239, at *11 (C.D. Cal. Sept. 19, 2018), *aff'd*, 793 F. App'x 608 (9th Cir. 2020).

[849] *See* JX-2359 (9/10/13 FDA Response to PROP Letter) (PPLPC019000835061), at -055, -059.

[850] *Ford Motor Co. v. Mont. Eighth Jud. Dist. Ct.*, 141 S.Ct. 1017, 1026-32 (2021); *Bristol-Myers Squibb Co. v. Superior Court of Cal.*, 137 S. Ct. 1773, 1783 (2017); *BNSF Ry. Co. v. Tyrrell*, 137 S. Ct. 1549, 1553-54 (2017); *Walden v. Fiore*, 571 U.S. 277, 291 (2014); *Daimler AG v. Bauman*, 571 U.S. 117, 136-39 (2014); *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 929-30 (2011); *J. McIntyre Mach., Ltd. v. Nicastro*, 564 U.S. 873, 886-87 (2011) (plurality opinion); *id.* at 888-89 (Breyer, J., concurring).

648. If the Shareholder Settlement and releases are not approved and the Non-Estate Claims revert to state court, the overwhelming majority of state courts are likely to lack personal jurisdiction over any of the Former Directors.

649. A defendant is subject to general jurisdiction in his or her home state. But almost all of the prepetition claims against the Former Directors relied on specific jurisdiction, which "depends on an 'affiliatio[n] between the forum and the underlying controversy,' principally, [an] activity or an occurrence that takes place in the forum State and is therefore subject to the State's regulation." *Goodyear*, 564 U.S. at 919.

650. Specific jurisdiction requires that the defendant "purposefully 'reach[ed] out beyond' his or her State and into another," *Walden*, 571 U.S. at 285, and that the claim against the defendant "arise[s] out of or relate[s] to the defendant's contacts with the forum." *Bristol-Myers Squibb*, 137 S. Ct. at 1780.

651. The Supreme Court cases teach that specific jurisdiction is narrowly construed:

- Targeting the United States as a whole is not a basis for personal jurisdiction in every state. *J. McIntyre Machinery*, 564 U.S. at 886-87 (plurality opinion), 888-89 (Breyer, J., concurring) (defendant's attempts to target the U.S. market did not support jurisdiction in New Jersey).
- It is not enough that the defendant's conduct had a foreseeable impact on individuals in the forum state. *Walden*, 571 U.S. at 291 (that defendant knew his conduct would have a foreseeable impact on residents in the forum state did not create personal jurisdiction there).
- A defendant's conduct in the forum state that is not claims-related does not create personal jurisdiction there. *Bristol-Myers Squibb*, 137 S. Ct. at 1783 (no jurisdiction over company with massive sales and research facilities in state, where claims had no connection to those jurisdictional contacts); *see also Ford Motor Co.*, 141 S. Ct. 1026 ("In the sphere of specific jurisdiction, the phrase 'relates to' incorporates real limits, as it must to adequately protect defendants foreign to the forum.").

2. Jurisdictional Theories Likely to Fail

a. Jurisdiction Based on Purdue's Conduct

652. Jurisdiction over a corporate officer or director cannot be based on jurisdiction over his or her corporation.[851] Accordingly, jurisdiction over the Former Directors cannot be predicated on the mere fact that Purdue engaged in business in a state.[852]

653. Claimants must show that each Former Director personally engaged in "suit-related conduct" that "create[d] a substantial connection with the forum State," and that the claims arise from or relate to that conduct. *Walden*, 571 U.S. at 284.

654. There is no evidence before the Court of an action that each Former Director took in, or targeted at, every State, let alone that each State's claims arise from or relate to those respective individual actions in or targeted at the forum state.

b. Jurisdiction Based on Assertions That the Former Directors Oversaw Purdue's Marketing

655. The cases overwhelmingly hold that officers and directors are not subject to personal jurisdiction on the theory that they "oversaw" or "controlled" corporate conduct. *See, e.g., Karabu Corp. v. Gitner*, 16 F. Supp. 2d 319, 324 (S.D.N.Y. 1998) (Sotomayor, D.J.); *Gerstle v. Nat'l Credit Adjusters, LLC*, 76 F. Supp. 3d 503, 510 (S.D.N.Y. 2015); *Fasugbe v. Willms*, 2011 WL 3667440, at *3-4 (E.D. Cal. Aug. 22, 2011); *Delman v. J. Crew Grp., Inc.*,

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[851] *See, e.g., Keeton v. Hustler Magazine, Inc.*, 465 U.S. 770, 781 n.13 (1984) ("[J]urisdiction over an employee does not automatically follow from jurisdiction over the corporation which employs him … . Each defendant's contacts with the forum State must be assessed individually.").

[852] *See, e.g.*, *Celtig, LLC v. Patey*, 347 F. Supp. 3d 976, 983-84 (D. Utah 2018) ("[Defendant] did not do business in Utah in his personal capacity and his role as CEO of a company doing business in the state of Utah is insufficient to subject him to personal jurisdiction in Utah."); *Harte-Hanks Direct Mktg./Balt., Inc. v. Varilease Tech. Fin. Grp.*, 299 F. Supp. 2d 505, 513 (D. Md. 2004) ("Personal jurisdiction over an individual officer, director, or employee of a corporation does not automatically follow from personal jurisdiction over a corporation.").

2017 WL 3048657, at *2 (C.D. Cal. May 15, 2017); *Flocco v. State Farm Mut. Auto. Ins. Co.*, 752 A.2d 147, 162-4 (D.C. Cir. 2000); *MFS Series Tr. III ex rel. MFS Mun. High Income Fund v. Grainger*, 96 P.3d 927, 931 (Utah 2004); *Coast to Coast Energy, Inc. v. Gasarch*, 149 A.D.3d 485, 487-88 (1st Dep't 2017).

656. To establish specific jurisdiction, there must be evidence that each of the Former Directors participated in Purdue's marketing or anti-diversion activities and that each one's conduct was either taken in, or targeted at, the forum state. There is no evidence before the Court supporting the assertion that any of them made decisions about what Purdue's marketing would say during the Relevant Period. As discussed *supra* at §VI, the evidence indicates that those decisions were made by Purdue's management. *See also* ¶¶264-65.

c. Jurisdiction Based on Purdue's National Marketing

657. The contention that the Former Directors controlled Purdue's nationwide marketing, apart from lacking factual support (*supra* §VI), is legally inadequate. Conduct directed at the nation as a whole does not automatically establish jurisdiction in every state. *J McIntyre Machinery*, 564 U.S. at 886 (Kennedy, J., plurality opinion); *id.* at 891 (Breyer, J., concurring). Lower court cases consistently reach the same result.[853]

[853] *See, e.g.*, *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 780 (3d Cir. 2018) ("what is necessary is a deliberate targeting of the forum, … so efforts 'to exploit a national market' that 'necessarily included Pennsylvania' are insufficient" to establish jurisdiction in Pennsylvania); *Puravai, LLC v. Blue Can*, 2018 WL 5085711, at *6 (D. Utah Oct. 18, 2018); *Mouzon v. Radiancy, Inc.*, 85 F. Supp. 3d 361, 372 (D.D.C. 2015); *Federated Rural Elec. Ins. Corp. v. Kootenai Elec. Co-op.*, 17 F.3d 1302, 1305 (10th Cir. 1994); *D'Jamoos ex rel. Estate of Weingeroff v. Pilatus Aircraft Ltd.*, 566 F.3d 94, 103-04 (3d Cir. 2009); *Rank v. Hamm*, 2007 WL 894565, at *12 (S.D. W. Va. Mar. 21, 2007); *Corwin v. Swanson*, 2010 WL 11598013, at *3 (C.D. Cal. Apr. 27, 2010); *Bhd. of Locomotive Eng'rs v. United Transp. Union*, 413 F. Supp. 2d 410, 420 (E.D. Pa. 2005).

d. Jurisdiction Based on Agency Theory

658. Personal jurisdiction cannot be asserted over the Former Directors on the theory that Purdue, or its employees, acted as their agents. On that argument, every director is subject to jurisdiction in every state, regardless of his or her individual conduct, which is exactly what *Keeton* rejected. Corporations are not the agents of their directors—directors are agents of their corporation.[854] The Supreme Court's precedent teaches that the conduct of others cannot be used to establish jurisdiction over a defendant.[855]

659. For agency to suffice, it is necessary to establish that the individual participated in *specific* corporate conduct aimed at the forum. *See, e.g.*, *Kreutter v. McFadden Oil Corp.*, 71 N.Y.2d 460, 467, 470 (1988). Generalized claims that a corporate officer or director controlled the company are insufficient to establish jurisdiction on an agency theory. *See, e.g.*, *Karabu*, 16 F. Supp. 2d at 324 (Sotomayor, D.J.); *Gerstle*, 76 F. Supp. 3d at 510; *Malden Transp., Inc. v. Uber Techs., Inc.*, 286 F. Supp. 3d 264, 271 (D. Mass. 2017).

e. Jurisdiction Based on Failure to Act

660. Many Non-Estate Claims are based on the theory that the Former Directors were negligent or reckless because they knew about the abuse of Purdue's products and failed to take

[854] 2 WILLIAM MEADE FLETCHER, CYCLOPEDIA OF THE LAW OF CORPORATIONS § 1066 (2020) (corporate "officers and agents are not agents of the directors but are agents of the corporation."); *Twin-Lick Oil Co. v. Marbury*, 91 U.S. 587, 589 (1875) ("The directors are the … agents of the corporation … ."); *Crowell v. Randell*, 35 U.S. 368, 382 (1836) (directors "are but agents of the corporation"); *Wilby v. Savoie*, 86 A.3d 362, 375-76 (R.I. 2014); *accord Monopoly Acquisitions, LLC v. T.E.N. Invs., Inc.*, 2007 WL 2726018, at *3 (D. Kan. Sept. 17, 2007); *Reedeker v. Salisbury*, 952 P.2d 577, 582 (Utah Ct. App. 1998).

[855] *See Keeton*, 465 U.S. at 781 n.13; *Walden*, 571 U.S. at 291 ("[I]t is the defendant, not the Plaintiffs or third parties, who must create contacts with the forum State."); *id.* at 284 (lawsuit "must arise out of contacts that the defendant *himself* creates with" the State) (emphasis in original).

some action. A failure to act, however, is not conduct targeted at a specific state, and personal jurisdiction cannot be premised on a defendant's knowledge of the conduct of others.[856]

H. Release and Untimeliness Defenses

661. Non-Estate Claims are likely barred to the extent that they are predicated on conduct outside of the Relevant Period.

1. Pre-2007 OxyContin Conduct Has Been Released by the States

662. The releases in Purdue's highly publicized 2007 State Consent Judgments and Medicaid Settlements with the District of Columbia and every state other than West Virginia (which had already settled in 2004 (¶49)) released claims against the Former Directors and their entities based on Purdue's marketing of OxyContin. Therefore, Non-Estate Claims based on OxyContin conduct occurring before mid-2007 are likely barred.

2. The Discovery Rule Is Likely Inapplicable

663. The discovery rule is unlikely available to extend limitations periods against the Former Directors for any out of time Non-Estate Claims based on Purdue's sales of opioids.

664. It is likely courts would find that the discovery rule does not apply because: (i) Purdue's 2007 Federal Guilty Plea put the world on notice of potential claims; (ii) in the 2007 Medicaid Settlements, the 49 Medicaid Settlement States reserved all non-Medicaid State claims and required that Purdue cooperate in future State investigations;[857] and (iii) the Non-Estate Claims are based on allegations that have been the subject of intense media attention for years.

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[856] *See, e.g.*, *Stewart v. Am. Ass'n of Physician Specialists, Inc.*, 2014 WL 2011799, at *4-5 (C.D. Cal. May 15, 2014); *Pettengill v. Curtis*, 584 F. Supp. 2d 348, 358-59 (D. Mass. 2008); *Chlebda v. H. E. Fortna & Bro., Inc.*, 609 F.2d 1022, 1023-24 (1st Cir. 1979).

[857] *See* JX-1898 (Form of State Settlement and Release) at ¶III.E.6.

665. Purdue's 2007 Federal Guilty Plea and associated admissions received extensive press coverage. ¶¶50-53. After the plea, OxyContin, its potential for abuse and addiction, and Purdue's marketing practices continued to receive enormous media attention. ¶54.

666. The Sackler families' association with Purdue, and receipt of billions in distributions, has also been a matter of media attention for years. ¶420.

667. Media stories constitute storm warnings that put all Claimants on notice of their claims.[858] Due diligence cannot be shown because, *inter alia*, State Claimants did not exercise their contractual power, under the 2007 Medicaid Settlements, to investigate Purdue. ¶215 n. 323.

II. THE ESTATE CLAIMS WILL LIKELY FAIL

668. In the Disclosure Statement, Debtors indicated that the Estate might have the following claims against the Sackler Family Members or related entities: fraudulent transfer claims, breach of fiduciary duty, veil-piercing, and unjust enrichment. Disclosure Statement at 138-39.

669. No Objector has submitted evidence or argument in support of these Estate Claims.

670. No Objector has objected on the ground that the Debtors' estates are receiving too little consideration for releasing these Claims.

[858] *See Hawk Mountain LLC v. Ram Capital Grp. LLC*, 689 F. App'x 703, 706 (3d Cir. 2017) (affirming dismissal of untimely claims because there were "[f]acing storm warnings the plaintiffs failed to exercise reasonable diligence to discovery their injuries"); *Ex parte Abbott Laboratories*, 2021 WL 2176897, at *12 (Ala. May 28, 2021) (dismissing public nuisance claim as untimely where "the opioid crisis began causing effects in the counties [plaintiff] serve[s] in 2012 or 2013. Despite that fact, [plaintiff] did not commence this action until October 2019.").

671. The record indicates that these claims will likely fail to achieve a significant recovery, especially in comparison to the Shareholder Settlement's benefits.

A. Fraudulent Transfer Claims

672. Debtors have stated that the Estates might have two types of fraudulent conveyance claims: actual fraudulent conveyance, on the theory that Sackler Family Members caused Purdue to make Distributions or Non-Cash Transfers "based on fears that Purdue ... was subject to potentially overwhelming liabilities for harms caused by opioids or for violations of law relating to marketing or other sales practices" (Disclosure Statement at 138-89), and constructive fraudulent conveyance, on the theory that Purdue became "legally insolvent as a result of accrued but unliquidated liabilities" (*id*.) before 2017, when Distributions stopped.

1. The Former Directors Have Presented Substantial Evidence That No 2008-16 Distribution or Non-Cash Transfer Was Made with Actual Intent to Defraud Creditors

673. Actual-intent fraudulent transfer claims require proof that the transferor—PPLP, in the case of the 2008-16 Distributions and Non-Cash Transfers—intended to prejudice Purdue's creditors.[859]

674. There is significant doubt that the Estates would be able to carry that burden.

675. The record shows that at the time of the 2008-16 Distributions and Non-Cash Transfers, there was no pending or anticipated litigation that threatened Purdue's solvency. ¶¶438-440.

676. As a result of Purdue's 2007 Guilty Plea, the 2007 State Consent Judgments and Medicaid Settlements, and an earlier settlement with West Virginia (¶¶30-49), the federal

[859] Under Article 10 of the DCL, as it existed at the time of the Distributions, a "conveyance made ... with actual intent, as distinguished from intent presumed in law, to hinder, delay, or defraud either present or future creditors, is fraudulent as to both present and future creditors." DCL § 276.

government and every state had, by mid-2007, released claims against Purdue based on Purdue's marketing of OxyContin for all periods preceding the releases. ¶¶42, 45, 47, 49.

677. The record indicates that there were relatively few product liability claims pending against Purdue between 2008 and 2017, fewer still that were not dormant, and that none of them posed a threat to Purdue's solvency. ¶¶439-440.

678. In the 2008-16 period, there were few governmental claims and investigations, and they were resolved for reasonable amounts. In 2015, Purdue settled an investigation by the New York Attorney General with a payment of just $75,000. ¶438; JX-1889 (AOD) (PPLP004035441) ¶38. In 2015, Purdue settled a longstanding litigation brought by the Attorney General of Kentucky for $24 million to be paid over 8 years, and that settlement was inflated because Purdue's outside counsel had been judicially determined to have admitted liability by failing to respond to requests for admission. ¶438.

679. From 2008 through 2019, PPLP paid a total of $342 million in settlements, excluding patent and other intellectual property disputes. ¶439. PPLP and associated companies earned net profits of $10.6 billion during a subset of this period, from 2008 to 2016.

680. The record reflects that Purdue's Board understood that Purdue was operating in compliance with law throughout the Relevant Period. ¶¶59, 121-122. No persuasive evidence has been adduced showing that Purdue's Board—which approved the Distributions and Non-Cash Transfers—knew that Purdue was acting unlawfully or that Purdue faced significant legal liabilities that it would be unable to pay.

681. The record reflects that Purdue was very profitable during the Relevant Period. Purdue regularly generated billions of dollars in annual revenue. ¶449. It had very large

amounts of unrestricted cash on hand every year. ¶¶451, 491. Purdue had no significant debt. ¶456.

682. The record does not indicate that the Board was told to expect that Purdue faced future litigation. To the contrary, numerous presentations to the Board indicate that the Board was told that Purdue would not face significant litigation. ¶¶458-463.

683. The record demonstrates that between 2014 and 2015, the Side B Directors proposed to reinvest Side B's Distributions back into Purdue as subordinated debt. ¶¶474-480. While this proposal was not accepted, it reflects a willingness by the Side B Directors to expose themselves to all the risks that Purdue faced. This contemporaneous evidence strongly suggests evidence that Side B directors did not anticipate the wave of litigation that led to Purdue's bankruptcy.

684. The record shows that from 2008 to 2017 the PPI Board authorized Purdue to spend over $2 billion on research and development. ¶¶481-486. This evidence tends to suggest that Purdue was being run for long-term success.

685. No evidence has been submitted showing that, at any point in 2008-16, the Former Directors anticipated the post-2016 opioid litigation that triggered Purdue's bankruptcy. It has been argued that documents from 2006 to 2008 evidence a fraudulent scheme by Sackler Family Members. *See* ¶¶487-530. These documents do not indicate that the Sackler Family Members were concerned about Purdue's solvency in 2008-16, when the Distributions and Non-Cash Transfers were made, and do not indicate that they participated in a fraudulent scheme. ¶¶487-530. No documents from 2009 to 2017 have been offered as supposed direct evidence that the Sackler Family Members were participating in a fraudulent scheme.

686. The record before the Court suggests that Debtors would likely not be able to present persuasive evidence showing that PPLP, PPI or the Sackler Family Members on the Board made the Distributions or Non-Cash Transfers with the intent to prejudice creditors. The evidence in the record tends to refute any assertion of fraudulent intent.

687. A consideration of the "badges of fraud" leads to the same result.

688. Badges of fraud sometimes provide circumstantial evidence of fraudulent intent, but the utility of such circumstantial evidence is limited where, as here, there is direct evidence that refutes fraudulent intent.[860]

689. The badges of fraud that could "give rise to an inference of intent to defraud" include:

> (1) gross inadequacy of consideration; (2) a close relationship between transferor and transferee; (3) the transferor's insolvency as a result of the conveyance; (4) a questionable transfer not in the ordinary course of business; (5) secrecy in the transfer; and (6) retention of control of the property by the transferor after the conveyance.[861]

690. "[T]he flip side of these badges of fraud is that their absence … would constitute evidence that there was no intent to defraud."[862]

691. Even if badges are present, evidence of a legitimate purpose can overcome a finding of fraudulent intent.[863]

692. The badges of fraud do not support an inference of fraudulent intent here.

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[860] *See In re Chin*, 492 B.R. 117, 132 (Bankr. E.D.N.Y. 2013) ("The availability of badges of fraud as circumstantial evidence fulfills an important function, but the utility of a checklist can only go so far."); *In re Stanton*, 457 B.R. 80, 94 (Bankr. D. Nev. 2011) ("Because they are only evidence of the likelihood of fraud, badges of fraud are not given equal weight; and sometimes the circumstances indicate they should be given no weight at all.").

[861] *Lippe v. Bairnco Corp.*, 249 F. Supp. 2d 357, 374-75 (S.D.N.Y. 2003), *aff'd*, 99 F. App'x 274 (2d Cir. 2004).

[862] *Lippe*, 249 F. Supp. 2d at 375.

[863] *In re Anderson*, 623 B.R. 199, 214 (Bankr. D. Conn. 2020).

693. The record indicates that the Distributions and Non-Cash Transfers were made in the ordinary course of business. The non-Tax Distributions occurred regularly and were subject to formal approval by PPI's Board. ¶419. The Tax Distributions were a longstanding practice of PPI and are a common feature of pass-through entities like PPLP. ¶550.

694. The Distributions and Non-Cash Transfers were not substantially all of Purdue's assets. They were a fraction of Purdue's net sales (¶¶452-455) and Purdue retained large amounts of cash after the Distributions and Non-Cash Transfers. (¶451).

695. No evidence has been offered indicating that the Distributions or Non-Cash Transfers were made in secrecy.

696. The concept of reasonably equivalent value is not relevant to the Non-Tax Distributions, which were made out of gross profits. The absence of consideration "is always the case in a dividends situation and it is a generally accepted practice for a corporation to pay dividends to its shareholders." *Lippe*, 249 F. Supp. 2d at 384.

697. There is nothing inherently suspicious about the close relationship between the Sackler Family Members and Purdue, given that Purdue was closely held. Standing alone, the close relationship between the Sackler Family Members and Purdue does not suggest an intent to defraud.

698. The Court concludes that the Debtors would likely struggle to prove any actual-intent fraudulent transfer claim.

2. Constructive Fraudulent Transfer Claims

699. To prove constructive fraudulent transfer, Debtors must establish that PPLP made a transfer for less than fair value—or less than "a reasonably equivalent value"—when it (i) was insolvent on a balance sheet basis, or the fair salable value of the its assets at the time of

the transaction was less than its probable liabilities (the "**Balance Sheet Test**"),[864] (ii) believed that it would incur debts beyond its ability to pay its debts as they came due (the "**Cash Flow Test**"), or (iii) was undercapitalized (the "**Capital Adequacy Test**").

700. The record before the Court indicates that the Debtors would likely fail to recover on a theory of constructive fraudulent transfer.

a. The Balance Sheet Test

701. The Balance Sheet Test considers whether the present fair salable value of Purdue's assets exceeded its liabilities at the time of each distribution. "Present fair salable value" is a market standard. *See In re Iridium Operating LLC*, 373 B.R. 283, 346-352 (Bankr. S.D.N.Y. 2007). Courts view "traditional valuation techniques and contemporaneous market evidence," including stock price and "assessments [by] market analysts" as "critical piece[s] of information in valuing a company." *Id*.

702. Professor Chakraborty, whose testimony is unchallenged, concludes (JX-1937 at ¶¶15), that Purdue was solvent under the Balance Sheet Test when each 2008-16 Distribution or Non-Cash Transfer was made because, using the highest reasonable estimate of Purdue's liabilities, the positive difference between its assets and its liabilities was never less than $1.3 billion and was as much as $9.2 billion. That conclusion is consistent with contemporaneous evidence showing that from 2008 to 2016, Purdue did not face or anticipate crippling litigation, and had large profits and substantial cash reserves even after the Distributions were made. ¶¶458-472.

[864] DCL §271. *See also* CONN. GEN. STAT. §52-552c; *In re LXEng LLC*, 607 B.R. 67, 97 (Bankr. D. Conn. 2019) ("To calculate a disputed claim's value properly, the court must assess the likelihood of the claim's success."), citing *Licata v. Coan*, 2015 WL 9699304, at *7 (D. Conn. Sept. 22, 2015), *aff'd sub nom. In re Licata*, 659 F. App'x 704 (2d Cir. 2016).

703. Solvency is judged as of "the time at which the transfer took place." *McCarthy v. Estate of McCarthy*, 145 F. Supp. 3d 278, 287 (S.D.N.Y. 2015). It is not judged with the benefit of hindsight. *Lippe*, 249 F. Supp. 2d at 380. "The hypothetical existence of liabilities, from future tort claims … is not considered for purposes of a fraudulent conveyance analysis." *FSP, Inc. v. Société Générale*, 2005 WL 475986, at *15 (S.D.N.Y. Feb. 28, 2005). The record before the Court does not suggest that the Pending Opioid Actions filed in 2017-19 or Purdue's 2020 Guilty Plea were anticipated during the period between 2008 and 2016. Accordingly, those lawsuits and that plea do not support a finding of retroactive insolvency.

b. The Cash Flow Test

704. The Cash Flow Test "requires proof of the transferor's subjective intent or belief that it will incur debt it cannot pay at maturity" at the time of the challenged transfer. *Innovative Custom Brands, Inc. v. Minor*, 2016 WL 308805, at *3 (S.D.N.Y. Jan. 25, 2016). A company fails the test if there was a "good indication of oncoming insolvency." *Grace Plaza of Great Neck, Inc. v. Heitzler*, 2 A.D.3d 780, 781 (2d Dep't 2003). The test applies an objective standard of reasonable foreseeability and requires only that the company's forecasts were "reasonable and prudent when made," not that the transferor had "resources sufficient to withstand any and all setbacks." *In re Bergman*, 293 B.R. 580, 584-85 (Bankr. W.D.N.Y. 2003).

705. The record indicates that Purdue was solvent under the Cash Flow Test because, using the highest reasonable estimate of Purdue's liabilities, its reasonably expected cash flows were sufficient to meet its reasonably expected liabilities as and when they would come due over a multi-year period, as Dr. Chakraborty's unchallenged testimony reflects. ¶427; JX-1937 (Chakraborty Rept.) ¶¶6, 16, 164-170.

c. The Capital Adequacy Test

706. The Capital Adequacy test "denotes a financial condition short of equitable insolvency" and "is aimed at transferees that leave the transferor technically solvent but doomed to fail." *MFS/Sun Life Tr.-High Yield Series v. Van Dusen Airport Servs. Co.,* 910 F. Supp. 913, 944 (S.D.N.Y. 1995). If a company makes a reasonable and prudent assessment that it has sufficient working capital to continue in business and manage reasonably foreseeable financial challenges, it does not have unreasonably small capital. *Id.*

707. The record reflects that Purdue was solvent under the Cash Flow Test because, using the highest reasonable estimate of Purdue's liabilities, it had an adequate amount of capital to sustain its operations under a stress-test scenario. Dr. Chakraborty so testified without contradiction. ¶427; JX-1937 (Chakraborty Rept.) ¶¶6, 16, 164-170.

708. This conclusion is lent further credence by the fact that Purdue remained in business over ten years after the earliest Distribution and two years after the last Distribution. Purdue's continued business operations for years after the Distributions and Non-Cash Transfers were made tends to support the conclusion that none of those transfers left Purdue with unreasonably small capital.

709. Accordingly, the Court concludes that it would be difficult for the Estates to prove that Purdue was insolvent at the time of the 2008-16 Distributions and Non-Cash Transfers, and that the Estates would likely not be able to recover them on a constructive fraudulent transfer theory.

d. The Tax Distributions

710. Debtors cannot recover, on a constructive fraudulent transfer theory, transfers for which they already received reasonably equivalent value. *See* DCL §273(a)(2).[865]

711. Reasonably equivalent value means that "the benefits the debtor receives … must approximate its expected costs."[866]

712. The Court concludes that the Tax Distributions were likely made for reasonably equivalent value.

713. Tax Distributions are a typical arrangement for pass-through entities like PPLP. JX-0425 (Blouin Report) ¶¶52-53.

714. Professor Blouin testified without contradiction that, from her perspective as an economist and a tax expert, the "tax distributions were made in exchange for bearing the tax obligation created by PPLP's economic activity." *Id.* at ¶59.

715. The amounts of Tax Distributions correlate with the amounts PPLP would have been obliged to pay had it been organized as a C corporation. *Id.* at ¶67 & Table 11; *see also* Blouin Supp. Decl. at ¶¶7-8 & Table 2. *See also* ¶¶545-546. The record indicates that the value of the tax distributions paid by PPLP during the 2008-17 Period was reasonably equivalent to the amount of taxes PPLP would have faced if it were organized as a C corporation during the same period. JX-0425 (Blouin Report) at ¶¶67-71; Blouin Supp. Decl. at ¶¶7-8.

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[865] Prior to April 4, 2020, New York's statute required the claimant to show that the transfer was for "fair consideration," rather than "reasonably equivalent value." However, for relevant purposes here, those two standards "have substantially the same meaning." *In re Sterman*, 594 B.R. 229, 234 (Bankr. S.D.N.Y. 2018).

[866] *In re Lyondell Chem. Co.*, 567 B.R. 55, 114 (Bankr. S.D.N.Y. 2017) (quoting *In re Jesup & Lamont, Inc.*, 507 B.R. 452, 472 (Bankr. S.D.N.Y. 2014), *aff'd*, 585 B.R. 41 (S.D.N.Y. 2018)).

716. Accordingly, the record reflects that the Tax Distributions were made for reasonably equivalent value in exchange for PPLP's owners' agreement to bear the tax obligation created by PPLP's economic activity. *See* JX-0425 (Blouin Report) at ¶71.

717. The Court concludes that it is unlikely the Debtors' Estates would be able to establish that the Tax Distributions should be set aside as constructive fraudulent transfers.

718. Additionally, the record indicates that the Tax Distributions have almost entirely been paid to state and federal governmental entities that filed Claims in these cases.

719. The record reflects that between 2008 and 2017, two Side B entities—the 74A Trust and Rosebay Medical Company, Inc.—received $2.261 billion in Tax Distributions from PPLP and paid almost 92%, or $2,072 billion, in taxes. *See* ¶549; *see also* JX-0425 (Blouin Report) ¶46.

720. It is unlikely that the Tax Distributions that were actually used to pay taxes would be avoided because doing so would be punitive and would not serve the remedial purpose of fraudulent conveyance law.[867] The Tax Distributions that were used to pay taxes are no longer in the possession of the recipients of those Distributions and have been taken by governmental Claimants. It would not be consistent with the purposes of fraudulent conveyance law for governmental Claimants to avoid the Tax Distributions that because that would lead to a double recovery.

721. Accordingly, the record before the Court indicates that the Estate would likely not be able to recover the Tax Distributions on a constructive fraudulent transfer theory.

[867] *See, e.g., In re Tronox Inc.*, 464 B.R. 606, 618 (Bankr. S.D.N.Y. 2012) ("[T]he purpose of fraudulent conveyance law is remedial rather than punitive"); *accord In re Keeley & Grabanski Land P'ship*, 531 B.R. 771, 777 & n.12 (B.A.P. 8th Cir. 2015) (quoting *Tronox*), *aff'd*, 832 F.3d 853 (8th. Cir. 2016).

B. Fiduciary Duty Claims

722. Debtors have stated that they "could potentially assert claims for breach of fiduciary duties against members of the Board." Disclosure Statement at 172.

723. The Debtors have stated that they might potentially assert a self-dealing claim. *Id.* The theory behind such a claim would be that the Former Directors should not have approved the Distributions and Non-Cash Transfers because they knew that Purdue faced substantial future legal liability. Such a claim would, as Debtors admit, "largely overlap in terms of evidence and substance" with the Estate's fraudulent transfer claims. *Id.* The Court concludes that the Debtors would struggle to recover on a self-dealing theory for the reasons they would be unlikely to prevail on a fraudulent transfer theory. *Supra* ¶¶673-721.

724. Debtors articulate two other potential theories of recovery on a breach of fiduciary duty claim.

725. The first is that the Former Directors "directly cause[d] the partnership to violate the law." Disclosure Statement at 172. As the Debtors' note, "there would ... have to be evidence tying such conduct to individual members of the Board." *Id.* at 173. No evidence has been adduced to support that theory. The Court notes that DOJ itself does not allege, in the Plea Agreement or Civil Settlement Agreement, that the Former Directors knew of the conduct admitted in the 2020 Guilty Plea.

726. The second theory is that the Former Directors "failed to implement or adequately monitor internal compliance programs" (Disclosure Statement at 172) at PPLP—a *Caremark* theory of recovery.[868]

[868] *In re Caremark Int'l Inc. Deriv. Litig.*, 698 A.2d 959 (Del. Ch. 1996).

727. As an initial matter, it is not clear that the Former Directors owed a *Caremark* duty to PPLP.

728. New York choice-of-law rules determine which state's law governs claims for breach of fiduciary duty. *In re Gaston & Snow*, 243 F.3d 599, 607 (2d Cir. 2001).

729. Under the internal affairs doctrine, Delaware law governs fiduciary duties owed to PPLP (a Delaware limited partnership) by its general partner, PPI,[869] and by PPI's Board,[870] while New York law governs fiduciary duties owed to PPI (a New York corporation) by its own Board.[871]

730. Under Delaware law, the duties owed by the directors of a corporate general partner like PPI to a limited partnership it manages are circumscribed. In *In re USACafes, L.P. Litigation*, 600 A.2d 43 (Del. Ch. 1991), the Delaware Chancery court recognized a limited duty of loyalty—which obligated them to refrain from self-dealing with respect to the limited partnership's property—but declined to find that the general partner's directors owed other fiduciary duties to the limited partnership. Delaware courts continue to adhere to *USACafes*' conclusion that directors of a corporate general partner owe only limited duties towards the limited partnership.[872] Those decisions have not held that the directors of a corporate partner

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869 *See, e.g.*, *Zutty v. Rye Select Broad Mkt. Prime Fund, L.P.*, 2011 WL 5962804 at *7 (N.Y. Sup. Ct., N.Y. Cnty. Apr. 15, 2011) ("claims ... of breach of duty pertaining to the conduct of [a Delaware limited partnership's] internal affairs, are governed by Delaware Law").

870 *See*, *e.g.*, *Spitzer v. Shanley Corp.*, 870 F. Supp. 565, 569-70 (S.D.N.Y. 1994) (applying Oklahoma law "to determine [the defendant's] personal responsibility as a director" of an Oklahoma limited partnership's corporate GP).

871 *See, e.g.*, *In re Ticketplanet.com*, 313 B.R. 46, 62 (Bankr. S.D.N.Y. 2004) ("the law of the state of incorporation governs an allegation of breach of fiduciary duty owed to a corporation")

872 *See, e.g.*, *Lewis v. AimCo Props., L.P.*, 2015 WL 557995, at *5 (Del. Ch. Feb. 10, 2015); *Bay Ctr. Apartments Owner, LLC v. Emery Bay PKI, LLC*, 2009 WL 1124451, at *9–10 (Del. Ch. Apr. 20, 2009).

owe a *Caremark* duty to the limited partnership's business. In *Wenske v. Blue Bell Creameries*, 2018 WL 3337531 at *17 (Del. Ch. July 6, 2018), the Chancery Court stated, in *dicta*, that a general partner's duties towards the limited partnership did not extend to a *Caremark* or *Caremark*-like duty of care.

731. Accordingly, the Debtors' *Caremark*-type claims may fail at the outset because no duty was owed.

732. Assuming that Debtors could establish that the Former Directors owed a *Caremark*-type duty towards PPLP, the Former Directors have presented substantial evidence establishing that they satisfied any *Caremark* duty they may have owed to PPLP.

733. *Caremark* requires that a board make a good faith effort to implement and monitor a reporting system designed to ensure compliance with law and attention to business risk:

> [I]t is important that the board exercise a good faith judgment that the corporation's information and reporting system is in concept and design adequate to assure the board that appropriate information will come to its attention in a timely manner as a matter of ordinary operations, so that it may satisfy its responsibility.

698 A.2d at 970. Caremark stresses that "the duty to act in good faith to be informed cannot be thought to require directors to possess detailed information about all aspects of the operation of the enterprise." *Id*. at 971 (emphasis added).

734. A finding of a *Caremark* violation, in the absence of red flags, requires a "showing that the board ever was aware that ... internal controls were inadequate, [and] that these inadequacies would result in illegal activity:"

> [G]ood faith in the context of oversight must be measured by the directors' actions to assure a reasonable information and reporting system exists and not by second-guessing after the occurrence of employee conduct that results in an unintended adverse outcome.

Stone v. Ritter, 911 A.2d 362, 370, 373 (Del. 2006).

735. "Where the board has in place a reasonable board-level system of monitoring and reporting, deference is given to the board and *Caremark* claims are dismissed even when illegal or harmful company activities escaped detection." *Behrmann v. Brandt*, 2020 WL 4432536, at *12 (D. Del. July 31, 2020).

736. The Former Directors have presented substantial evidence that Purdue put in place and monitored compliance systems, including compliance systems to address diversion and ensure that marketing complied with the law. ¶¶142-207.

737. The record reflects (¶¶59-143) that Purdue had in place a rigorous and "regular protocol requiring board-level reports about the relevant risks" and that there were "third-party monitors, auditors, or consultants" who also reviewed the compliance systems. *Behrmann*, 2020 WL 4432536, at *12 (dismissing *Caremark* claim where plaintiff "acknowledge[d] the existence of board-level monitoring and oversight systems").

738. No evidence has been submitted indicating that the Board ignored any red flags during the Relevant Period. Purdue pleaded guilty in 2007. But Purdue's compliance procedures were designed to address that guilty plea and avoid repetition of similar misconduct, initially being overseen by the HHS OIG and the IRO because of the guilty plea.

739. The record that Debtors are unlikely to be able to prevail on a *Caremark* theory of liability.

C. Veil Piercing Claims

740. Debtors have asserted that the Estates could bring a claim on a veil-piercing theory.[873] The record indicates that Debtors would have difficulty prevailing on such a claim.

[873] Disclosure Statement at 174.

1. <u>Veil Piercing PPLP</u>

741. Because PPLP is a limited partnership, it has no "corporate veil" that can be pierced. *See In re Heritage Org. LLC*, 413 B.R. 438, 514 n.64 (Bankr. N.D. Tex. 2009) (applying Delaware law) ("the alter ego theory cannot be used to pierce the entity veil of [limited partnerships]") (applying Delaware law).

742. PPI is PPLP's general partner, and PRALP is its limited partner. ¶257. Under governing Delaware law[874] "a general partner of a limited partnership has the liabilities of a partner," DEL. CODE ANN. TIT. 6, §17-403(b), while a limited partner "is <u>not liable</u> for the obligations of a limited partnership unless … he or she participates in the control of the business" and, then, is liable only to "persons who transact business with the limited partnership reasonably believing" that it is the general partner. DEL. CODE ANN. TIT. 6, §17-303 (emphasis added).

743. There is no evidence in the record that PRALP, the limited partner of PPLP, had authority to control PPLP's business or that PRALP actually controlled or participated in PPLP's business.

2. <u>Veil-Piercing PPI</u>

744. PPI is a New York corporation. Veil piercing a New York corporation requires proof that : "(1) the owners exercised complete domination of the corporation with respect to the transaction attacked; and (2) that such domination was used to commit a fraud or wrong against the plaintiff, which resulted in plaintiff's injury."[875]

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874 *In re Saba Enters., Inc.*, 421 B.R. 626, 648 (Bankr. S.D.N.Y. 2009).

875 *Morris v. N.Y. State Dep't of Taxation and Fin.*, 82 N.Y.2d 135, 141-42 (1993).

745. The record does not support a finding that any one person, or either Side A or Side B, dominated PPI.

746. The record reflects that the day-to-day business of Purdue was managed by a team of executives, none of whom was a member of the Sackler Family during the Relevant Period. ¶¶256-264.

747. The record reflects that neither Side A nor Side B could control the PPI Board because the approval of both a majority of each of the Side A and Side B directors was required for any Board action. ¶266.

748. The record reflects that the different Sackler Family Members who served on the PPI Board sometimes disagreed both with each other and with independent directors elected on their behalf. ¶270.

749. The record does not support a finding that PPI's corporate form was abused. An alter ego claim requires evidence "that the owners, through their domination, abused the privilege of doing business in the corporate form to perpetrate a wrong or injustice against that party."[876] Courts evaluating whether owners abused the corporate form examine whether the company was just a "sham or shell,"[877] or whether it had a "legitimate business purpose."[878]

750. While the record indicates that Purdue engaged in criminal activity, that does not support a finding that PPI was a sham or not a legitimate business. The record indicates that Purdue was managed as a business that generated billions of dollars in revenue from the sale of

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[876] *Morris*, 82 N.Y.2d at 142.

[877] *Nat'l Gear & Piston, Inc. v. Cummins Power Sys., LLC*, 975 F. Supp. 2d 392, 406 (S.D.N.Y. 2013).

[878] *CSX Transp., Inc. v. Filco Carting Corp.*, 2011 WL 2713487, at *3 (E.D.N.Y. July 11, 2011) ("Where the defendant has a 'legitimate business purpose' itself, the court should not disregard the corporate structure.).

FDA-approved prescription medications. There is no dispute that it did, in fact, develop, manufacture, and sell such medications for decades. No evidence has been adduced suggesting that Purdue was established to defraud creditors or that the finances of the members of the Sackler Family were intermixed with Purdue's finances.

751. The Court concludes that Debtors are unlikely to be able to pierce the corporate veil to hold PPI's owners liable for PPI's debts.

3. Veil-Piercing beyond PPI

752. PPI is not directly owned by Sackler Family Members. It is owned by entities, which are in turn owned by trusts for the benefit of certain Sackler Family Members.

753. In order to obtain a veil-piercing remedy, Debtors must not only pierce the PPI corporate form, but also the corporate form of entities that own it and the entities that own them, until Debtors reached the assets that they seek to recoup.[879]

754. No evidence in the record supports piercing the corporate form of those entities. Nothing in the record suggests that those corporations were shams.

755. The Court concludes that Debtors are unlikely to be able to pierce the corporate veil beyond PPI.

4. The Single Enterprise Theory

756. The Disclosure Statement at 134 references the "single enterprise theory" of alter ego recovery.

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[879] *See* JX-1915 (Martin Report, Ex. A — 11/2019 Raymond-Side Informational Presentation); *In re Gulf Fleet Holdings, Inc.*, 491 B.R. 747, 790 (Bankr. W.D. La. 2013) (plaintiff seeking veil-piercing against members of a corporate structure must "establish alter ego liability with respect to each one of the entities" in that structure); *In re Heritage Org. LLC*, 413 B.R. at 514-15 (Bankr. N.D. Tex. 2009) (rejecting "global application" of an alter-ego theory because plaintiff failed to allege veil-piercing "at each layer of ownership … within the multi-faceted entity structure").

757. As an initial matter, it is not clear that such a doctrine exists in New York apart from traditional alter ego liability.

758. Even assuming it does exist, there is no basis on this record to disregard traditional rules of corporate separateness. No evidence has been offered to show that Purdue's management ran the IACs or that the management of any of the IACs ran Purdue. No evidence has been offered to show that the PPI Board managed the IACs or that the MNP Board (which advised the IACs) managed PPI.

759. The fact that the IACs and Purdue were both indirectly owned by the Sacklers does not support veil-piercing under the single enterprise theory.

D. <u>Unjust Enrichment</u>

760. The Disclosure Statement states that the Debtors might have potential unjust enrichment claims against recipients of "the various cash and unvalued non-cash transfers" out of Purdue "based on the same set of facts" as Debtors' claims for fraudulent transfer.[880]

761. The Court concludes that such claims are unlikely to succeed for largely the same reasons that the Debtors' fraudulent transfer claims are unlikely to succeed.

762. The record does not support a finding that the challenged Distributions were made improperly. §IX, *supra*. The record does not contain evidence showing that the Former Directors participated in unlawful conduct at Purdue. §VI, *supra*. The record reflects that the Former Directors acted on the understanding that Purdue had in place compliance systems to

[880] Disclosure Statement at 172.

prevent unlawful conduct. §§III-IV, *supra*. These circumstances indicate that the Debtors likely cannot show that Purdue's owners retaining lawfully paid Distributions would be unjust.[881]

763. Additionally, any unjust enrichment claim would likely fail because courts routinely reject the use of unjust enrichment claims to circumvent defects in other claims. Therefore, the Debtors could not use an unjust enrichment claim to circumvent the defects in their fraudulent transfer and veil-piercing claims. *See, e.g.*, *In re Boston Generating LLC,* 617 B.R. 442, 475-76 (Bankr. S.D.N.Y. 2020) (dismissing unjust enrichment claim that duplicated fraudulent transfer claims); *Bigio v. Coca-Cola Co.*, 675 F.3d 163, 171, 177 (2d Cir. 2012) (affirming dismissal of unjust enrichment claim against shareholders where plaintiff had not justified piercing the corporate veil).

764. Additionally, any unjust enrichment claim would likely be subject to a three year statute of limitations. Under New York law, the statute of limitations for an unjust enrichment claim depends on the nature of the substantive remedy the plaintiff seeks. "The limitations period is six years where a plaintiff seeks an equitable remedy, but three years where a plaintiff seeks monetary damages."[882] Because Debtors' unjust enrichment claim would seek monetary damages, the limitations period is at most three years.[883] Consequently, Debtors' potential unjust enrichment claims apply at most to the less than $300 million in Distributions made after

[881] *See Inv'rs Liquidated Trust v. Dimenna*, 2019 WL 7050139 at *11 (D. Conn. Dec. 23 2019) ("it was not 'unlawful' for [owners] to receive distributions from entities in which they invested both money … and time …").

[882] *In re Boston Generating LLC*, 617 B.R. 442 at 469 (applying three-year limitations period to unjust enrichment claim).

[883] *See Access Point Med., LLC v Mandell*, 106 A.D.3d 40, 43-44 (1st Dep't 2013) (plaintiff cannot avoid the three year limitations period by characterizing its unjust enrichment claim as seeking equitable relief because the court "cannot allow a purely semantic distinction" about what claims for money are called "to control the application of the statute of limitations").

September 15, 2016 (three years before bankruptcy was commenced)—of which $233.5 million comprised Tax Distributions.

765. Accordingly, Debtors are unlikely to be able to recover a significant amount, if anything, on an unjust enrichment theory.

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766. **Final Conclusion of Law.** To the extent that any Finding of Fact may be deemed a Conclusion of Law, it is hereby incorporated by reference.